

CUMULATIVE
SUPPLEMENT 8
AUGUST 2000

APPROVED DRUG PRODUCTS

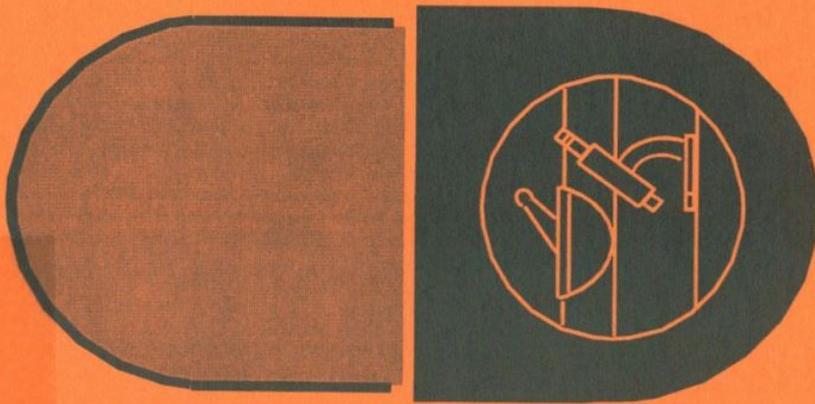
WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

20TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF INFORMATION TECHNOLOGY
DIVISION OF DATA MANAGEMENT AND SERVICES

2000

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2000
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Class
S.O.

Prepared By
Division of Data Management and Services
Office of Information Technology
Center for Drug Evaluation and Research
Food and Drug Administration

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

20TH EDITION

Cumulative Supplement 8

August 2000

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

20TH EDITION

CUMULATIVE SUPPLEMENT 8
AUGUST 2000

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 20th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Patent and Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the patent and/or exclusivity expires. Refer to the Patent and Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations. Information regarding drug patents and exclusivity for an approved product will appear in this addendum as it is received and may not correspond with the month the drug product is approved and published in the Rx/OTC sections of the Cumulative Supplement.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to place an asterisk (*) to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement.

Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision. [Strength(s) which already exist in the List will not be repeated for context.]

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

New additions to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is then dropped in subsequent Cumulative Supplements for that item.

New deletions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >DLT> (DELETE) to the left of the line. The >DLT> symbol is dropped in subsequent Cumulative Supplements for that item. The shaded print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements (hard copy only) for this edition.

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 20th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 21st Edition.

1.2 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When

this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section

APPLICANT NAME CHANGES

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

GALDERMA LABS INC
(GALDERMA)

GALDERMA LABORATORIES LP
(GALDERMA LABS LP)

GLOBAL PHARMACEUTICAL CORP
(GLOBAL PHARM)

IMPAX LABORATORIES INC
(IMPAX LABS)

HOECHST MARION ROUSSEL INC
(HOECHST MARION RSSL)

AVENTIS PHARMACEUTICALS INC
(AVENTIS PHARMS)

RHONE POULENC RORER PHARMACEUTICALS INC
(RHONE POULENCE RORER)

AVENTIS PHARMACEUTICALS PRODUCTS INC
(AVENTIS PHARM PROD)

ROCHE GLOBAL DEVELOPMENT
(ROCHE GLOBAL)

ROCHE GLOBAL A DIVISION OF SYNTEX (USA) LLC
(ROCHE GLOBAL DEV)

SYNTEX (USA) INC
(SYNTEX)

SYNTEX (USA) LLC
(SYNTEX (USA) LLC)

SYNTEX FP INC
(SYNTEX)

SYNTEX (USA) LLC
(SYNTEX (USA) LLC)

SYNTEX LABORATORIES INC
SUB SYNTEX CORP
(SYNTEX)

SYNTEX (USA) LLC
(SYNTEX (USA) LLC)

SYNTEX USA INC
(SYNTEX)

SYNTEX (USA) LLC
(SYNTEX (USA) LLC)

TAP HOLDINGS INC
(TAP HOLDINGS)

TAP PHARMACEUTICAL PRODUCTS INC
(TAP PHARM)

ZENECA INC
(ZENECA)

ASTRAZENECA PHARMACEUTICALS LP
(ASTRAZENECA PHARMS)

ZENECA LTD
(ZENECA)

ASTRAZENECA UK LTD
(ASTRAZENECA UK)

ZENECA PHARMACEUTICALS DIV ZENECA INC
(ZENECA)

ASTRAZENECA PHARMACEUTICALS LP
(ASTRAZENECA PHARMS)

1.3 DICLOFENAC SODIUM OPHTHALMIC SOLUTION 0.1%

Two NDAs have been approved for diclofenac sodium ophthalmic solution 0.1% (DSOS), (1) Ciba's NDA 20-037 for Voltaren and (2) Falcon Pharms' (Alcon) NDA 20-809 for DSOS. Alcon was required to do a study comparing their DSOS to Voltaren and to a placebo control in post cataract surgical inflammation. This study was necessary to demonstrate that the different formulation of the Alcon drug product did not affect the safety and/or effectiveness of the proposed drug product for this indication. Prior to the approval of Alcon's DSOS Ciba did clinical studies and was approved for two additional indications for the temporary relief of pain and photophobia in patients undergoing corneal refractive surgery. Three years of Waxman-Hatch marketing exclusivity was granted to Ciba for these two new uses.

Since the treatment of pain has a different site of action than the anti-inflammatory or photophobia indications the Agency did not have information to support a recommendation that the Alcon and Ciba DSOS are therapeutically equivalent for the treatment of pain. The designation of therapeutic equivalence at this time applies only to the anti-inflammatory indication. The therapeutic equivalence designation will apply to the photophobia indication upon expiration of Ciba's marketing exclusivity.

1.4 AVAILABILITY OF THE EDITION

The 20th Edition of the Orange Book and its monthly cumulative supplements are available by subscription from the Government Printing Office:

Superintendent of Documents
Government Printing Office
P.O. Box 371954
Pittsburgh, PA 15250-7954

The telephone number to charge your subscription is 202-512-1800. The cost is \$90.00 annually.

The Approved Drug Products with Therapeutic Equivalence Evaluation (Orange Book) and related drug information is also available on the Internet at the Food and Drug Administration, Center for Drug Evaluation and Research, Drug Info page.

There is an Electronic Orange Book Query (EOB) at <http://www.fda.gov/cder/ob>. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder or applicant number. Product search categories are: prescription, over-the-counter, discontinued drugs. There are links to patent and exclusivity information that may be applicable to each product. The data is updated concurrently with the publication of the annual edition or monthly cumulative supplements.

The Internet version of the hard copy Orange Book annual edition is at <http://www.fda.gov/cder/orange/adp.htm>.

The Internet version of the hard copy monthly supplement is at <http://www.fda.gov/cder/orange/supplement/cspreface.htm>. Changes to the annual edition are listed separately by month.

There are ASCII text files of the Orange Book drug product data at <http://www.fda.gov/cder/orange/obreadme.htm>. The drug product text files are zipped into zipobtxt.exe. The files are updated concurrently with the publication of the annual edition or monthly cumulative supplements. Appendix A and Appendix B are updated quarterly.

The 20th annual edition of the 1999 Orange Book Patent and Exclusivity List is at <http://www.fda.gov/cder/orange/20bookpub.pdf>.

The current year Patent and Exclusivity cumulative supplement list that denotes the current month additions is at <http://www.fda.gov/cder/orange/supplement/patents.pdf>.

The Drug Price Competition and Patent Term Restoration Act requires that patent information be filed with all newly submitted Section 505 drug applications. To facilitate industry submission of the information, a patent submission sample format is available in HTML and PDF format at:
<http://www.fda.gov/cder/orange/patdecl.pdf>
<http://www.fda.gov/cder/orange/patdecl.html>

The current listing of the Orphan Product Designations and Approvals is available at <http://www.fda.gov/orphan/designat/list.htm>.

1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under section 505 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 1999) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER

| <u>CATEGORIES COUNTED</u> | <u>DEC 1999</u> | <u>MAR 2000</u> | <u>JUN 2000</u> | <u>SEP 2000</u> |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
| DRUG PRODUCTS LISTED | 10045 | 10082 | 10186 | |
| SINGLE SOURCE | 2599 (25.9%) | 2596 (25.7%) | 2617 (25.7%) | |
| MULTISOURCE | 7335 (73.0%) | 7375 (73.2%) | 7458 (73.2%) | |
| THERAPEUTICALLY EQUIVALENT | 6986 (69.5%) | 7040 (69.8%) | 7132 (70.0%) | |
| NOT THERAPEUTICALLY EQUIVALENT | 349 (3.5%) | 335 (3.3%) | 326 (3.2%) | |
| EXCEPTIONS ¹ | 111 (1.1%) | 111 (1.1%) | 111 (1.1%) | |
| NEW MOLECULAR ENTITIES APPROVED | 0 | 6 | 11 | |
| NUMBER OF APPLICANTS | 576 | 575 | 580 | |

¹Amino acid-containing products of varying composition (see Introduction, page xx of the List).

PRESCRIPTION DRUG PRODUCT LIST
20TH EDITION
RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN'2000 - AUG'2000

| | | | | | |
|----------------------------------|---|----------------------------|--------------|--|--------------|
| <u>ACETAMINOPHEN; BUTALBITAL</u> | | | | | |
| | TABLET; ORAL | | | | |
| | <u>PHRENILIN FORTE</u> | | | | |
| <u>AB</u> | + AMARIN PHARMS | <u>650MG; 50MG</u> | N88831 001 | | N40355 001 |
| | | | JUN 19, 1985 | | MAY 31, 2000 |
| <u>AB</u> | * CARRICK | <u>650MG; 50MG</u> | N88831 001 | | N40356 001 |
| | | | JUN 19, 1985 | | MAY 31, 2000 |
| | TABLET; ORAL | | | | |
| | <u>PHRENILIN</u> | | | | |
| <u>AB</u> | + AMARIN PHARMS | <u>325MG; 50MG</u> | N87811 001 | | N40358 001 |
| | | | JUN 19, 1985 | | MAY 31, 2000 |
| <u>AB</u> | * CARRICK | <u>325MG; 50MG</u> | N87811 001 | | N40094 003 |
| | | | JUN 19, 1985 | | AUG 08, 2000 |
| | <u>ACETAMINOPHEN; CODEINE PHOSPHATE</u> | | | | |
| | SUSPENSION; ORAL | | | | |
| | <u>ACETAMINOPHEN AND CODEINE PHOSPHATE</u> | | | | |
| <u>AA</u> | AMARIN PHARMS | <u>120MG/5ML; 12MG/5ML</u> | N86024 001 | | N40099 001 |
| | | | N86024 001 | | JUN 25, 1997 |
| <u>AA</u> | CARRICK | <u>120MG/5ML; 12MG/5ML</u> | N86024 001 | | N40099 001 |
| | | | | | AUG 08, 2000 |
| | <u>ACETAMINOPHEN; HYDROCODONE BITARTRATE</u> | | | | |
| | TABLET; ORAL | | | | |
| | <u>HYDROCODONE BITARTRATE AND ACETAMINOPHEN</u> | | | | |
| <u>AA</u> | VINTAGE PHARMS | <u>325MG; 10MG</u> | | | N40148 001 |
| | | | | | FEB 14, 1997 |
| <u>AA</u> | | <u>500MG; 10MG</u> | | | N40148 001 |
| | | | | | FEB 14, 1997 |
| <u>AA</u> | | <u>660MG; 10MG</u> | | | |
| | | | | | |
| <u>AA</u> | WATSON LABS | <u>660MG; 10MG</u> | | | |
| | | | | | |
| | LORTAB | | | | |
| | UCB | <u>325MG; 5MG</u> | | | |
| | | | | | |
| | @ | <u>325MG; 5MG</u> | | | |
| | | | | | |
| | NORCO | | | | |
| <u>AA</u> | + WATSON LABS | <u>325MG; 10MG</u> | | | N40148 001 |
| | | | | | FEB 14, 1997 |
| | * | <u>325MG; 10MG</u> | | | N40148 001 |
| | | | | | FEB 14, 1997 |
| | <u>ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE</u> | | | | |
| | TABLET; ORAL | | | | |
| | <u>PENTAZOCINE HCL AND ACETAMINOPHEN</u> | | | | |
| <u>AB</u> | WATSON LABS | <u>650MG; EQ 25MG BASE</u> | | | N74699 001 |
| | | | | | MAR 24, 2000 |
| <u>AB</u> | TALACEN | | | | |
| | + SANOFI SYNTHELABO | <u>650MG; EQ 25MG BASE</u> | | | N18458 001 |
| | | | | | SEP 23, 1982 |
| | * | <u>650MG; EQ 25MG BASE</u> | | | N18458 001 |
| | | | | | SEP 23, 1982 |
| | <u>ACETOHEXAMIDE</u> | | | | |
| | TABLET; ORAL | | | | |
| | <u>ACETOHEXAMIDE</u> | | | | |
| <u>AB</u> | BARR | <u>500MG</u> | | | N70870 001 |
| | | | | | FEB 09, 1987 |
| <u>AB</u> | | <u>500MG</u> | | | N70870 001 |
| | | | | | FEB 09, 1987 |
| | | | | | |
| <u>AB</u> | DYMELOR | <u>250MG</u> | | | N13378 002 |
| | LILLY | <u>500MG</u> | | | N13378 001 |
| | | | | | N13378 002 |
| | @ | <u>250MG</u> | | | |

ALPRAZOLAM

TABLET; ORAL
ALPRAZOLAM
ROXANE

| | | | |
|---------|-----------|---------------|--------------|
| > DLT > | <u>AB</u> | <u>0.25MG</u> | N74199 001 |
| > DLT > | | | OCT 19, 1993 |
| > DLT > | <u>AB</u> | <u>0.5MG</u> | N74199 002 |
| > DLT > | | | OCT 19, 1993 |
| > DLT > | <u>AB</u> | <u>1MG</u> | N74199 003 |
| > DLT > | | | OCT 19, 1993 |
| > ADD > | @ | 0.25MG | N74199 001 |
| > ADD > | | | OCT 19, 1993 |
| > ADD > | @ | 0.5MG | N74199 002 |
| > ADD > | | | OCT 19, 1993 |
| > ADD > | @ | 1MG | N74199 003 |
| > ADD > | | | OCT 19, 1993 |

AMINO ACIDS

INJECTABLE; INJECTION
NOVAMINE 15% SULPITE FREE IN PLASTIC CONTAINER
BAXTER HLTHCARE

| | | |
|---|-----|--------------|
| @ | 15% | N20107 001 |
| | | FEB 05, 1993 |
| | | N20107 001 |
| | | FEB 05, 1993 |
| | | N19018 001 |
| | | JUL 20, 1984 |
| | | N19018 001 |
| | | JUL 20, 1984 |
| | | N19018 003 |
| | | SEP 07, 1988 |
| | | N19018 003 |
| | | SEP 07, 1988 |

TROPHAMINE
B BRAUN

TROPHAMINE 10%
B BRAUN

ALTRETAMINE

CAPSULE; ORAL
HEXALEN

| | | |
|-----------------|------|--------------|
| * US BIOSCIENCE | 50MG | N19926 001 |
| | | DEC 26, 1990 |
| | | N19926 001 |
| | | DEC 26, 1990 |

AMINOPHYLLINE

TABLET; ORAL
AMINOPHYLLINE
GLOBAL PHARM

| | | |
|-----------|--------------|------------|
| <u>AB</u> | <u>100MG</u> | N84574 001 |
| <u>AB</u> | <u>200MG</u> | N84574 001 |
| @ | 100MG | N84574 001 |
| @ | 200MG | N84574 001 |

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL
AMANTADINE HCL
GENEVA PHARMS TECH

| | | |
|-----------|--------------|--------------|
| <u>AB</u> | <u>100MG</u> | N71293 001 |
| | | FEB 18, 1987 |
| <u>AB</u> | <u>100MG</u> | N71293 001 |
| | | FEB 18, 1987 |

AMIODARONE HYDROCHLORIDE

TABLET; ORAL
AMIODARONE HCL
+ EON

| | | |
|--|-------|--------------|
| | 400MG | N75315 002 |
| | | JUN 30, 2000 |

AMIFOSTINE

INJECTABLE; INJECTION
ETHYOL

| | | |
|-----------------|------------|--------------|
| * US BIOSCIENCE | 500MG/VIAL | N20221 001 |
| | | DEC 08, 1995 |
| | | N20221 001 |
| | | DEC 08, 1995 |

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL
ME PHARM

| | | | |
|---------|-----------|--------------|------------|
| > DLT > | <u>AB</u> | <u>10MG</u> | N85864 001 |
| > DLT > | <u>AB</u> | <u>25MG</u> | N85935 001 |
| > DLT > | <u>AB</u> | <u>50MG</u> | N85936 001 |
| > DLT > | <u>AB</u> | <u>75MG</u> | N86337 001 |
| > DLT > | <u>AB</u> | <u>100MG</u> | N86336 001 |
| > DLT > | <u>AB</u> | <u>150MG</u> | N86335 001 |
| > ADD > | @ | 10MG | N85864 001 |

@ MEDEVA PHARMS CA

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

AMITRIPTYLINE HCL

@ MEDEVA PHARMS CA .

> ADD > 25MG N85935 001 N20227 001
 > ADD > 50MG N85936 001 MAY 23, 1997
 > ADD > 75MG N86337 001 N20227 002
 > ADD > 100MG N86336 001 MAY 23, 1997
 > ADD > 150MG N86335 001 N20227 001
 > ADD > N86335 001 MAY 23, 1997

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

TABLET; ORAL

ADDERALL 12.5

SHIRE RICHWOOD

> ADD > 3.125MG;3.125MG;3.125MG; N11522 012
 > ADD > 3.125MG AUG 31, 2000

ADDERALL 15

SHIRE RICHWOOD

> ADD > 3.75MG;3.75MG;3.75MG; N11522 013
 > ADD > 3.75MG AUG 31, 2000

ADDERALL 7.5

SHIRE RICHWOOD

> ADD > 1.875MG;1.875MG;1.875MG; N11522 011
 > ADD > 1.875MG AUG 31, 2000
 > ADD >

ANAGRELIDE HYDROCHLORIDE

CAPSULE; ORAL

AGRYLIN

ROBERTS LABS

EQ 0.5MG BASE

EQ 1MG BASE

EQ 0.5MG BASE

EQ 1MG BASE

+ > ADD > N20333 001 N20333 001
 > ADD > MAR 14, 1997 MAR 14, 1997
 > ADD > N20333 002 N20333 002
 > ADD > MAR 14, 1997 MAR 14, 1997

ARDEPARIN SODIUM

INJECTABLE; INJECTION

NORMIFLO

+ PHARMACIA AND UPJOHN 5,000 UNITS/0.5ML

N20227 002

MAY 23, 1997

ARDEPARIN SODIUM

INJECTABLE; INJECTION

NORMIFLO

+ PHARMACIA AND UPJOHN 10,000 UNITS/0.5ML

N20227 001

MAY 23, 1997

N20227 002

MAY 23, 1997

N20227 001

MAY 23, 1997

* WYETH AYERST 5,000 UNITS/0.5ML

* IO,000 UNITS/0.5ML

ARGATROBAN

INJECTABLE; INJECTION

ACOVA

+ TX BIOTECH 100MG/ML

N20883 001

JUN 30, 2000

ARTICAINE HYDROCHLORIDE; EPINEPHRINE

INJECTABLE; INJECTION

SEPTOCAINE

+ DEPROCO 4*;EQ 0.01MG BASE/ML

N20971 001

APR 03, 2000

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PANTOTHENIC ACID; PHYTONADIONE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; VITAMIN A PALMITATE; VITAMIN E

INJECTABLE; INJECTION

KABIVITE PED F + W KIT

* FRESSENIUS KABI

N/A,80MG/VIAL;N/A,0.02MG/VIAL;N/A,

0.001MG/VIAL;400 IU/10ML,N/A;N/A,

0.14MG/VIAL,N/A,17MG/VIAL;N/A,

5MG/VIAL;0.2MG/10ML,N/A;N/A,

1MG/VIAL;N/A,1.4MG/VIAL;N/A,

1.2MG/VIAL;EQ 2,300 UNITS BASE/10ML,

N/A;7 IU/10ML,N/A N20176 001

DEC 29, 1993

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PANTOTHENIC ACID; PHYTONADIONE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; VITAMIN A PALMITATE; VITAMIN E

INJECTABLE; INJECTION
VITAPED
© FRESenius KABI

N/A, 80MG/VIAL; N/A, 0.02MG/VIAL; N/A,
0.001MG/VIAL; 400 IU/10ML, N/A; N/A,
0.14MG/VIAL; N/A, 1.7MG/VIAL; N/A,
5MG/VIAL; 0.2MG/10ML, N/A; N/A,
1MG/VIAL; N/A, 1.4MG/VIAL; N/A,
1.2MG/VIAL; EQ 2.300 UNITS BASE/10ML,
N/A; 7 IU/10ML, N/A
N20176 001
DEC 29, 1993

ATOVAQUONE; PROGUANIL HYDROCHLORIDE

TABLET; ORAL
MALARONE
+ GLAXO WELLCOME 250MG; 100MG N21078 001
JUL 14, 2000
MALARONE PEDIATRIC
+ GLAXO WELLCOME 62.5MG; 25MG N21078 002
JUL 14, 2000

ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE

TABLET; ORAL
MOTOFEN
+ AMARIN PHARMS 0.025MG; 1MG N17744 002
* CARRICK 0.025MG; 1MG N17744 002
MOTOFEN HALF-STRENGTH
© AMARIN PHARMS 0.025MG; 0.5MG N17744 001
© CARRICK 0.025MG; 0.5MG N17744 001

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
DIPHENOXYLATE HCL AND ATROPINE SULFATE
PAR PHARM 0.025MG; 2.5MG N40357 001
MAY 02, 2000

ATROPINE SULFATE; EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION
ENLON-PLUS
+ BAXTER PHARM PROD 0.14MG/ML; 1.0MG/ML N19677 001
NOV 06, 1991
+ 0.14MG/ML; 1.0MG/ML N19678 001
NOV 06, 1991
* OHMEDA 0.14MG/ML; 1.0MG/ML N19677 001
NOV 05, 1993
* 0.14MG/ML; 1.0MG/ML N19678 001
NOV 06, 1991

AZELASTINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
OPTIVAR
+ ASTA 0.05% N21127 001
MAY 22, 2000

BALSALAZIDE DISODIUM

CAPSULE; ORAL
COLAZAL
+ SALIX 750MG N20610 001
JUL 18, 2000

BENZTROPINE MESYLATE

TABLET; ORAL
BENZTROPINE MESYLATE
AA GENEVA PHARMS TECH 0.5MG N72264 001
FEB 27, 1989
AA 1MG N72265 001
FEB 27, 1989
AA 2MG N72266 001
FEB 27, 1989
AA INVAMED 0.5MG N72264 001
FEB 27, 1989
AA 1MG N72265 001
FEB 27, 1989
AA 2MG N72266 001
FEB 27, 1989

BETAXOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

BETAXOLOL

AT AKORN

EQ 0.5% BASE

N75386 001
JUN 30, 2000

AT + ALCON

EQ 0.5% BASE

N19270 001
AUG 30, 1985

EQ 0.5% BASE

N19270 001
AUG 30, 1985

BETHANECHOL CHLORIDE

INJECTABLE; INJECTION

URECHOLINE

* MERCK

@

5MG/ML

N06536 001
N06536 001

TABLET; ORAL

BETHANECHOL CHLORIDE

DANBURY PHARMA

AA

10MG

N84408 001

AA

25MG

N84441 001

AA

50MG

N87444 001

@

10MG

N84408 001

@

25MG

N84441 001

@

50MG

N87444 001

DUVOID

ROBERTS LABS

AA

10MG

N86262 001

AA

25MG

N86263 001

@

50MG

N85882 003

MYOTONACHOL

GLENWOOD

AA

5MG

N84188 001

AA

10MG

N84188 003

AA

25MG

N84188 004

@

5MG

N84188 001

@

10MG

N84188 003

@

25MG

N84188 004

URECHOLINE

* MERCK

@

5MG

N06536 003

@

10MG

N06536 002

@

25MG

N06536 004

@

50MG

N06536 005

@

5MG

N06536 003

@

10MG

N06536 002

BETHANECHOL CHLORIDE

TABLET; ORAL

URECHOLINE

@ MERCK

25MG

N06536 004

@

50MG

N06536 005

+ ODYSSEY PHARMS

5MG

N89095 001

+

10MG

DEC 19, 1985

+

25MG

N88440 001

+

50MG

MAY 29, 1984

+

50MG

N89096 001

AA *

5MG

DEC 19, 1985

AA *

10MG

N89095 001

AA *

25MG

DEC 19, 1985

AA *

50MG

MAY 29, 1984

AA *

50MG

DEC 19, 1985

BEXAROTENE

GEL; TOPICAL

TARGETIN

+ LIGAND

1%

N21056 001

JUN 28, 2000

BLEOMYCIN SULFATE

INJECTABLE; INJECTION

BLEOMYCIN

AP FAULDING

EQ 15 UNITS BASE/VIAL

N65031 001

EQ 30 UNITS BASE/VIAL

MAR 10, 2000

AP

EQ 15 UNITS BASE/VIAL

MAR 10, 2000

AP

EQ 30 UNITS BASE/VIAL

MAR 10, 2000

AP

GENSIA SICOR PHARMS

N65033 001

AP

EQ 30 UNITS BASE/VIAL

JUN 27, 2000

EQ 15 UNITS BASE/VIAL

N65033 002

EQ 30 UNITS BASE/VIAL

JUN 27, 2000

CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

SOLUTION; PERFUSION, CARDIAC
 CARDIOLEGIC IN PLASTIC CONTAINER
 AT BAXTER HLTHCARE 17.6MG/100ML; 325.3MG/100ML;
 119.3MG/100ML; 643MG/100ML N75323 001
 APR 21, 2000

PLEGISOL IN PLASTIC CONTAINER
 AT + ABBOTT 17.6MG/100ML; 325.3MG/100ML;
 119.3MG/100ML; 643MG/100ML N18608 001
 FEB 26, 1982
 * 17.6MG/100ML; 325.3MG/100ML;
 119.3MG/100ML; 643MG/100ML N18608 001
 FEB 26, 1982

CANDICIDIN
 OINTMENT; VAGINAL
 VANOBID
 @ AVENTIS PHARMS 0.6MG/GM N61596 001
 * HOECHST MARION RSSL 0.6MG/GM N61596 001

TABLET; VAGINAL
 VANOBID
 @ AVENTIS PHARMS 3MG N61613 001
 * HOECHST MARION RSSL 3MG N61613 001

CAPTOPRIL; HYDROCHLOROTHIAZIDE
 TABLET; ORAL
 CAPTOPRIL AND HYDROCHLOROTHIAZIDE
 AB DANBURY PHARMA 50MG; 25MG N74832 001
 DEC 29, 1997
 @ 50MG; 25MG N74832 001
 DEC 29, 1997

CARBIDOPA; LEVODOPA
 TABLET, EXTENDED RELEASE; ORAL
 CARBIDOPA AND LEVODOPA
 AB MYLAN 25MG; 100MG N75091 002
 APR 21, 2000
 SINEMET CR
 AB DUPONT PHARMS 25MG; 100MG N19856 002
 DEC 24, 1992

CARBIDOPA; LEVODOPA

TABLET, EXTENDED RELEASE; ORAL
 SINEMET CR
 DUPONT PHARMS 25MG; 100MG N19856 002
 DEC 24, 1992

CARTEOLOL HYDROCHLORIDE
 SOLUTION/DROPS; OPHTHALMIC
 CARTEOLOL HCL
 AT ALCON 1% N75476 001
 JAN 03, 2000

AT BAUSCH AND LOMB 1% N75546 001
 JAN 20, 2000

AT OCUPRESS 1% N19972 001
 MAY 23, 1990
 * AT CIBA 1% N19972 001
 MAY 23, 1990

CEFAZOLIN SODIUM
 INJECTABLE; INJECTION
 CEFAZOLIN AND DEXTROSE
 + B BRAUN EQ 500MG BASE/VIAL N50779 001
 JUL 27, 2000
 + EQ 1GM BASE/VIAL N50779 002
 JUL 27, 2000

CEFAZOLIN SODIUM
 AM PHARM PARTNERS EQ 1MG BASE/VIAL N64169 002
 AUG 14, 1998
 AP EQ 1GM BASE/VIAL N64169 002
 AUG 14, 1998

CEFDINIR
 CAPSULE; ORAL
 OMNICEF
 + ABBOTT 300MG N50739 001
 DEC 04, 1997
 * PARKE DAVIS 300MG N50739 001
 DEC 04, 1997

POWDER FOR RECONSTITUTION; ORAL
 OMNICEF
 + ABBOTT 125MG/5ML N50749 001
 DEC 04, 1997

CEFDINIR

POWDER FOR RECONSTITUTION; ORAL

OMNICEF

* PARKE DAVIS

125MG/5ML

N50749 001
DEC 04, 1997

CEFOTAXIME SODIUM

INJECTABLE; INJECTION

CEFOTAXIME

AM PHARM PARTNERS

EQ 500MG BASE/VIAL

N64200 001
MAR 24, 2000

EQ 1GM BASE/VIAL

N64200 002
MAR 24, 2000

EQ 2GM BASE/VIAL

N64200 003
MAR 24, 2000

EQ 10GM BASE/VIAL

N64201 001
MAR 24, 2000

EQ 20GM BASE/VIAL

N64201 002
MAR 24, 2000

CLAFORAN

+ AVENTIS PHARMS

EQ 500MG BASE/VIAL

N50547 001
DEC 29, 1983

EQ 1GM BASE/VIAL

N50547 002
DEC 29, 1983

EQ 2GM BASE/VIAL

N50547 003
DEC 29, 1983

EQ 10GM BASE/VIAL

N50547 004
DEC 29, 1983

* HOECHST MARION RSSI

EQ 500MG BASE/VIAL

N50547 001
DEC 29, 1983

EQ 1GM BASE/VIAL

N50547 002
DEC 29, 1983

EQ 2GM BASE/VIAL

N50547 003
DEC 29, 1983

EQ 10GM BASE/VIAL

N50547 004
DEC 29, 1983

CEFOXITIN SODIUM

INJECTABLE; INJECTION

CEFOXITIN

AM PHARM PARTNERS

EQ 1GM BASE/VIAL

N65012 001
JUL 03, 2000

EQ 2GM BASE/2VIAL

N65012 002
JUL 03, 2000

EQ 10GM BASE/VIAL

N65011 001
JUL 03, 2000

MEFOXIN

+ MERCK

EQ 1GM BASE/VIAL

N50517 001
JAN 08, 1987

EQ 1GM BASE/VIAL

N62757 001
JAN 08, 1987

CEFOXITIN SODIUM

INJECTABLE; INJECTION

MEFOXIN

+ MERCK

EQ 2GM BASE/VIAL

N50517 002
JAN 08, 1987

EQ 2GM BASE/VIAL

N62757 002
JAN 08, 1987

EQ 10GM BASE/VIAL

N50517 003
JAN 08, 1987

EQ 1GM BASE/VIAL

N50517 001
JAN 08, 1987

EQ 1GM BASE/VIAL

N62757 001
JAN 08, 1987

EQ 2GM BASE/VIAL

N50517 002
JAN 08, 1987

EQ 2GM BASE/VIAL

N62757 002
JAN 08, 1987

EQ 10GM BASE/VIAL

N50517 003
JAN 08, 1987

CEFTIBUTEN DIHYDRATE

CAPSULE; ORAL

CEDEX

+ DJ PHARMA

EQ 400MG BASE

N50685 002
DEC 20, 1995

EQ 400MG BASE

N50685 002
DEC 20, 1995

* SCHERING PLOUGH

POWDER FOR RECONSTITUTION; ORAL

CEDEX

+ DJ PHARMA

EQ 90MG BASE/5ML

N50686 001
DEC 20, 1995

EQ 180MG BASE/5ML

N50686 002
DEC 20, 1995

EQ 90MG BASE/5ML

N50686 001
DEC 20, 1995

EQ 180MG BASE/5ML

N50686 002
DEC 20, 1995

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION

ROCEPHIN

+ HLR

EQ 250MG BASE/VIAL

N50585 001
DEC 21, 1984

EQ 250MG BASE/VIAL

N63239 001
AUG 13, 1993

EQ 500MG BASE/VIAL

N50585 002
DEC 21, 1984

> ADD >

> ADD >

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION

ROCEPHIN

HLR

EQ 500MG BASE/VIAL

EQ 1GM BASE/VIAL

EQ 1GM BASE/VIAL

EQ 1GM BASE/VIAL

EQ 2GM BASE/VIAL

EQ 2GM BASE/VIAL

EQ 10GM BASE/VIAL

EQ 250MG BASE/VIAL

EQ 250MG BASE/VIAL

EQ 500MG BASE/VIAL

EQ 500MG BASE/VIAL

EQ 1GM BASE/VIAL

EQ 1GM BASE/VIAL

EQ 1GM BASE/VIAL

EQ 2GM BASE/VIAL

EQ 2GM BASE/VIAL

EQ 10GM BASE/VIAL

ROCEPHIN W/ DEXTROSE IN PLASTIC CONTAINER

EQ 10MG BASE/ML

EQ 20MG BASE/ML

EQ 40MG BASE/ML

EQ 10MG BASE/ML

EQ 20MG BASE/ML

N63239 002

AUG 13, 1993

N50585 003

DEC 21, 1984

N62654 002

APR 30, 1987

N63239 003

AUG 13, 1993

N50585 004

DEC 21, 1984

N62654 003

APR 30, 1987

N50585 005

DEC 21, 1984

N50585 001

DEC 21, 1984

N63239 001

AUG 13, 1993

N50585 002

DEC 21, 1984

N63239 002

AUG 13, 1993

N50585 003

DEC 21, 1984

N62654 002

APR 30, 1987

N63239 003

AUG 13, 1993

N50585 004

DEC 21, 1984

N62654 003

APR 30, 1987

N50585 005

DEC 21, 1984

ROCEPHIN W/ DEXTROSE IN PLASTIC CONTAINER

EQ 10MG BASE/ML

EQ 20MG BASE/ML

EQ 40MG BASE/ML

EQ 10MG BASE/ML

EQ 20MG BASE/ML

> ADD >

> DLT >

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION

ROCEPHIN W/ DEXTROSE IN PLASTIC CONTAINER

EQ 40MG BASE/ML

ROCHE

CEFTRIAXONE SODIUM; LIDOCAINE

INJECTABLE; INJECTION

ROCEPHIN KIT

+ HLR

+ HLR

* ROCHE

* ROCHE

N50624 003

FEB 11, 1987

EQ 1GM BASE/VIAL,N/A,N/A, N50585 006

1 ‡ MAY 08, 1996

EQ 500MG BASE/VIAL,N/A,N/A, N50585 007

1 ‡ MAY 08, 1996

EQ 1GM BASE/VIAL,N/A,N/A, N50585 006

1 ‡ MAY 08, 1996

EQ 500MG BASE/VIAL,N/A,N/A, N50585 007

1 ‡ MAY 08, 1996

CEPHALEXIN

POWDER FOR RECONSTITUTION; ORAL

KEFLEX

* LILLY

* LILLY

* LILLY

* LILLY

* LILLY

* LILLY

EQ 125MG BASE/5ML

EQ 250MG BASE/5ML

EQ 250MG BASE/5ML

EQ 250MG BASE/5ML

EQ 125MG BASE/5ML

EQ 250MG BASE/5ML

N50406 001

N50406 002

N62117 003

N62117 003

N50406 001

N50406 002

CERIVASTATIN SODIUM

TABLET; ORAL

BAYCOL

* BAYER

* BAYER

* BAYER

* BAYER

* BAYER

* BAYER

N20740 005

MAY 24, 1999

N20740 005

MAY 24, 1999

N20740 006

JUL 24, 2000

| | | | | | |
|--------------------------------|----------------------|-------------------|--------------|--|--------------|
| <u>CISPLATIN</u> | | | | | |
| INJECTABLE; INJECTION | | | | | |
| <u>CISPLATIN</u> | | | | | |
| AP | PHARMACHEMIE | <u>1MG/ML</u> | N74656 001 | | N50615 001 |
| | | | MAY 16, 2000 | | JAN 07, 1987 |
| | | | | | N50615 001 |
| | | | | | JAN 07, 1987 |
| <u>CITALOPRAM HYDROBROMIDE</u> | | | | | |
| TABLET; ORAL | | | | | |
| CELEXA | | | | | |
| FOREST LABS | | | | | |
| * | | | | | |
| + | | | | | |
| @ | | | | | |
| <u>CLADRIBINE</u> | | | | | |
| INJECTABLE; INJECTION | | | | | |
| <u>CLADRIBINE</u> | | | | | |
| AP | BEDFORD | <u>1MG/ML</u> | N75405 001 | | N21142 001 |
| | | | FEB 28, 2000 | | MAY 26, 2000 |
| <u>CLARITHROMYCIN</u> | | | | | |
| TABLET; ORAL | | | | | |
| BIAXIN | | | | | |
| | ABBOTT | 250MG | N50662 001 | | N75368 001 |
| | | | OCT 31, 1991 | | FEB 15, 2000 |
| + | | 250MG | N50662 001 | | |
| | | | OCT 31, 1991 | | |
| TABLET, EXTENDED RELEASE; ORAL | | | | | |
| BIAXIN XL | | | | | |
| + | ABBOTT | 500MG | N50775 001 | | N75731 003 |
| | | | MAR 03, 2000 | | APR 27, 2000 |
| | | | | | N75731 002 |
| | | | | | APR 27, 2000 |
| | | | | | N75731 001 |
| | | | | | APR 27, 2000 |
| <u>CLINDAMYCIN PHOSPHATE</u> | | | | | |
| GEL; TOPICAL | | | | | |
| CLEOCIN T | | | | | |
| AB | PHARMACIA AND UPJOHN | <u>EQ 1% BASE</u> | | | N50615 001 |
| | | | | | JAN 07, 1987 |
| * | | | | | |
| | | | | | |
| <u>CLINDAMYCIN PHOSPHATE</u> | | | | | |
| AB | ALTANA | <u>EQ 1% BASE</u> | | | N64160 001 |
| | | | | | JAN 28, 2000 |
| SOLUTION; TOPICAL | | | | | |
| <u>CLINDAMYCIN PHOSPHATE</u> | | | | | |
| AT | CLAY PARK | <u>EQ 1% BASE</u> | | | N65049 001 |
| | | | | | MAY 25, 2000 |
| <u>CLOBETASOL PROPIONATE</u> | | | | | |
| AEROSOL; TOPICAL | | | | | |
| OLUX FOAM | | | | | |
| + | CONNETICS | 0.05% | | | |
| CREAM; TOPICAL | | | | | |
| <u>CLOBETASOL PROPIONATE</u> | | | | | |
| AB2 | TARO | <u>0.05%</u> | | | N75633 001 |
| | | | | | MAY 17, 2000 |
| GEL; TOPICAL | | | | | |
| <u>CLOBETASOL PROPIONATE</u> | | | | | |
| AB | ALTANA | <u>0.05%</u> | | | N75368 001 |
| | | | | | FEB 15, 2000 |
| CLORAZEPATE DIPOTASSIUM | | | | | |
| TABLET; ORAL | | | | | |
| <u>CLORAZEPATE DIPOTASSIUM</u> | | | | | |
| AB | TARO | <u>3.75MG</u> | | | N75731 003 |
| | | | | | APR 27, 2000 |
| AB | | <u>7.5MG</u> | | | N75731 002 |
| | | | | | APR 27, 2000 |
| AB | | <u>15MG</u> | | | N75731 001 |
| | | | | | APR 27, 2000 |

CYCLOSPORINE

AB CAPSULE; ORAL
CYCLOSPORINE
EON

25MG N65017 002
100MG N65017 001
25MG N50715 001
50MG N50715 003
100MG N50715 002

EQ 5MG BASE/ML N50731 001
EQ 5MG BASE/ML N65035 001
EQ 5MG BASE/VIAL N64212 002

AB NEORAL
NOVARTIS

25MG N50715 001
50MG N50715 003
100MG N50715 002

EX CAPSULE; ORAL
DECLOMYCIN
LEDERLE
EX CAPSULE; ORAL
DECLOMYCIN
LEDERLE
EX * 100MG N50715 002
100MG N50715 002
100MG N50715 002

150MG N50262 001
150MG N50262 001

AB SOLUTION; ORAL
CYCLOSPORINE
ABBOTT

100MG/ML N65025 001
100MG/ML N64195 001
100MG/ML N64195 001

0.004MG/ML N75220 001
0.004MG/ML N74575 001
0.004MG/ML N74574 001

DAUNORUBICIN CITRATE

AB INJECTABLE, LIPOSOMAL; INJECTION
DAUNOXOME
GILEAD
AB * INJECTABLE, LIPOSOMAL; INJECTION
DAUNOXOME
GILEAD

EQ 2MG BASE/ML N50704 002
EQ 2MG BASE/ML N50704 002
EQ 2MG BASE/ML N50704 002

0.15MG/SPRAY N20355 001
0.15MG/SPRAY N20355 001
0.15MG/SPRAY N20355 001

DAUNORUBICIN HYDROCHLORIDE

AB INJECTABLE; INJECTION
DAUNORUBICIN HCL
BEDFORD
AB * INJECTABLE; INJECTION
DAUNORUBICIN HCL
BEDFORD

EQ 5MG BASE/ML N50731 001
EQ 5MG BASE/ML N50731 001

0.15MG, N/A; 0.02MG, 0.01MG N20713 001
0.15MG, N/A; 0.02MG, 0.01MG N20713 001
0.15MG, N/A; 0.02MG, 0.01MG N20713 001

DAUNORUBICIN HYDROCHLORIDE

AB INJECTABLE; INJECTION
DAUNORUBICIN HCL
BEDFORD
AB * INJECTABLE; INJECTION
DAUNORUBICIN HCL
BEDFORD

EQ 5MG BASE/ML N50731 001
EQ 5MG BASE/ML N65035 001
EQ 5MG BASE/VIAL N64212 002

AB GENSIA SICOR PHARMS

DEMECLOCYCLINE HYDROCHLORIDE

AB CAPSULE; ORAL
DECLOMYCIN
LEDERLE
AB * CAPSULE; ORAL
DECLOMYCIN
LEDERLE
AB * CAPSULE; ORAL
DECLOMYCIN
LEDERLE

150MG N50262 001
150MG N50262 001

DESMOPRESSIN ACETATE

AB INJECTABLE; INJECTION
DESMOPRESSIN ACETATE
ABBOTT
AB INJECTABLE; INJECTION
DESMOPRESSIN ACETATE
ABBOTT

0.004MG/ML N75220 001
0.004MG/ML N74575 001
0.004MG/ML N74574 001

AB SPRAY, METERED; NASAL
STIMATE
ABBOTT
AB * SPRAY, METERED; NASAL
STIMATE
ABBOTT

0.15MG/SPRAY N20355 001
0.15MG/SPRAY N20355 001
0.15MG/SPRAY N20355 001

DESOGESTREL; ETHINYL ESTRADIOL

AB TABLET; ORAL-28
MIRCETTE
ORGANON
AB * TABLET; ORAL-28
MIRCETTE
ORGANON

0.15MG, 0.02MG N20713 001
0.15MG, 0.02MG N20713 001
0.15MG, 0.02MG N20713 001

DEXAMETHASONE, NEOMYCIN SULFATE, POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC
NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE
 0.1%; EQ 3.5MG BASE/ML;
 10,000 UNITS/ML N62721 001
 NOV 17, 1986
 AT STERIS
 0.1%; EQ 3.5MG BASE/ML;
 10,000 UNITS/ML N62721 001
 NOV 17, 1986

DEXAMETHASONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC, OTIC
DEXAMETHASONE SODIUM PHOSPHATE
 EQ 0.1% PHOSPHATE N88771 001
 JAN 16, 1985
 AT SOLUTION/DROPS; OPHTHALMIC, OTIC
DEXAMETHASONE SODIUM PHOSPHATE
 EQ 0.1% PHOSPHATE N88771 001
 JAN 16, 1985

DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE

SOLUTION/DROPS; OPHTHALMIC
NEOMYCIN SULFATE-DEXAMETHASONE SODIUM PHOSPHATE
 EQ 0.1% PHOSPHATE;
 EQ 3.5MG BASE/ML N62714 001
 JUL 21, 1986
 AT STERIS
 EQ 0.1% PHOSPHATE;
 EQ 3.5MG BASE/ML N62714 001
 JUL 21, 1986

DEZOCINE

INJECTABLE; INJECTION
 DALGAN 5MG/ML N19082 001
 * ASTRAZENECA 1.0MG/ML N19082 002
 DEC 29, 1989
 * 1.5MG/ML N19082 003
 DEC 29, 1989
 @ 5MG/ML N19082 001
 DEC 29, 1989

DEZOCINE

INJECTABLE; INJECTION
 DALGAN 10MG/ML N19082 002
 @ ASTRAZENECA 15MG/ML N19082 003
 DEC 29, 1989

DIAZEPAM

> ADD > INJECTABLE; INJECTION N19287 001
 > ADD > DIZAC JUN 18, 1993
 > ADD > @ PHARMACIA AND UPJOHN 5MG/ML
 > ADD >
 > DLT > INJECTABLE; INTRAVENOUS N19287 001
 > DLT > DIZAC JUN 18, 1993
 > DLT > * PHARMACIA AND UPJOHN 5MG/ML
 > DLT >

DICLOFENAC POTASSIUM

TABLET; ORAL
DICLOFENAC POTASSIUM 50MG N75229 001
 GENEVA PHARMS TECH NOV 20, 1998
 AB INVAMED 50MG N75229 001
 NOV 20, 1998

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC †
DICLOFENAC SODIUM 0.1% N20809 001
 FALCON PHARMS MAY 04, 1998
 @ 0.1% N20809 001
 MAY 04, 1998
 * VOLTAREN N20037 001
 * CIBA MAR 28, 1991
 + N20037 001
 MAR 28, 1991
 TABLET, EXTENDED RELEASE; ORAL
DICLOFENAC SODIUM 100MG N75492 001
 AB BIOVAIL FEB 11, 2000

† SEE SECTION 1.3 OF INTRODUCTION

DICLOFENAC SODIUM

TABLET, EXTENDED RELEASE; ORAL

VOLTAREN-XR

AB + NOVARTIS

100MG

100MG

N20254 001

MAR 08, 1996

N20254 001

MAR 08, 1996

DIENESTROL

SUPPOSITORY; VAGINAL

DV

0.7MG

0.7MG

@ AVENTIS PHARMS

* HOECHST MARION RSSI

N83517 001

N83517 001

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

DIETHYLPROPION HCL

AA MD PHARM

@ MEDEVA PHARMS CA

25MG

25MG

N85544 001

N85544 001

DIFLORASONE DIACETATE

CREAM; TOPICAL

DIFLORASONE DIACETATE

TARO

0.05%

N75508 001

APR 24, 2000

> DLT >
> ADD >

DILTIAZEM MALATE

TABLET, EXTENDED RELEASE; ORAL

TIAMATE

* HOECHST MARION RSSI

EQ 120MG HCL

EQ 180MG HCL

EQ 240MG HCL

+ MERCK

EQ 120MG HCL

EQ 180MG HCL

EQ 240MG HCL

N20506 001

OCT 04, 1996

N20506 002

OCT 04, 1996

N20506 003

OCT 04, 1996

N20506 001

OCT 04, 1996

N20506 002

OCT 04, 1996

N20506 003

OCT 04, 1996

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

AA GLOBAL PHARM

IMPAX LABS

25MG

50MG

25MG

50MG

N80807 001

N80807 002

N80807 001

N80807 002

DIVALPROEX SODIUM

TABLET, EXTENDED RELEASE; ORAL

DEPAKOTE ER

+ ABBOTT

EQ 500MG VALPROIC ACID

N21168 001

AUG 04, 2000

> ADD >
> ADD >
> ADD >
> ADD >

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

DILTIAZEM HCL

BIOVAIL

120MG

180MG

240MG

300MG

N20939 001

JAN 28, 2000

N20939 002

JAN 28, 2000

N20939 003

JAN 28, 2000

N20939 004

JAN 28, 2000

DOXEPIN HYDROCHLORIDE

CREAM; TOPICAL

ZONALON

+ BIOGLAN PHAR

* MEDICIS

N20126 001

APR 01, 1994

N20126 001

APR 01, 1994

INJECTABLE; INJECTION

DILTIAZEM HCL

ABBOTT

5MG/ML

N75004 001

FEB 16, 2000

ENFLURANE

LIQUID; INHALATION

ETHRANE

AN + BAXTER PHARM PROD
AN * CHEMEDA

99.9%
99.9%

N17087 001
N17087 001

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL

ERGOMAR

AA LOTUS BIOCHEN

2MG

N87693 001
FEB 24, 1983

+

2MG

N87693 001
FEB 24, 1983

ERGOSTAT

AA PARKE DAVIS

2MG

N88337 001
JUN 08, 1984

@

2MG

N88337 001
JUN 08, 1984

WIGRETTES

AA * ORGAVON

2MG

N86750 001
JUL 29, 1982

@

2MG

N86750 001
JUL 29, 1982

ERYTHROMYCIN

SOLUTION; TOPICAL

SANSAC

AT GALDERMA LABS

2%

N62522 001
JAN 24, 1985

AT HEALTHPOINT

2%

N62522 001
JAN 24, 1985

ERYTHROMYCIN ETHYLSUCCINATE

GRANULE; ORAL

PEDIAMYCIN

AB ROSS LABS

EQ 200MG BASE/5ML

N62305 001

@

EQ 200MG BASE/5ML

N62305 001

SUSPENSION/DROPS; ORAL

PEDIAMYCIN

* ROSS LABS

EQ 100MG BASE/2.5ML

N62305 002

@

EQ 100MG BASE/2.5ML

N62305 002

ERYTHROMYCIN ETHYLSUCCINATE

TABLET; CHEWABLE; ORAL

PEDIAMYCIN

AB ROSS LABS

EQ 200MG BASE

N62305 001

@

EQ 200MG BASE

N62306 001

ESTRADIOL

CREAM; VAGINAL

ESTRACE

* BRISTOL MYERS SQUIEB 0.01%

N86069 001

+ WARNER CHILCOTT

0.01%

N86069 001

JAN 31, 1984

FILM, EXTENDED RELEASE; TRANSDERMAL

CLIMARA

AB + BERLEX LABS

0.05MG/24HR

N20375 001

DEC 22, 1994

AB +

0.1MG/24HR

N20375 002

DEC 22, 1994

BX *

0.05MG/24HR

N20375 001

DEC 22, 1994

BX *

0.1MG/24HR

N20375 002

DEC 22, 1994

ESTRADIOL

BX CYGNUS CA

0.05MG/24HR

N21048 001

SEP 20, 1999

BX

0.075MG/24HR

N21048 002

SEP 20, 1999

BX

0.1MG/24HR

N21048 003

SEP 20, 1999

@ JOHNSON RW

0.05MG/24HR

N21048 001

SEP 20, 1999

@

0.075MG/24HR

N21048 002

SEP 20, 1999

@

0.1MG/24HR

N21048 003

SEP 20, 1999

AB MYLAN TECHNOLOGIES

0.05MG/24HR

N75233 001

FEB 24, 2000

AB

0.1MG/24HR

N75182 001

FEB 24, 2000

VIVELLE

0.025MG/24HR

N20323 005

AUG 16, 2000

> ADD >

> ADD >

ESTRADIOL

TABLET; ORAL
ESTRADIOL
APPLIED ANAL

| | | |
|-----------|--------------|--------------|
| <u>AB</u> | 0.5MG | N40138 001 |
| | | JAN 30, 1998 |
| <u>AB</u> | <u>1MG</u> | N40138 002 |
| | | JAN 30, 1998 |
| <u>AB</u> | <u>2MG</u> | N40138 003 |
| | | JAN 30, 1998 |
| <u>AB</u> | <u>0.5MG</u> | N40138 001 |
| | | JAN 30, 1998 |
| <u>AB</u> | <u>1MG</u> | N40138 002 |
| | | JAN 30, 1998 |
| <u>AB</u> | <u>2MG</u> | N40138 003 |
| | | JAN 30, 1998 |

ENDEAVOR

ETHANOLAMINE OLEATE

INJECTABLE; INJECTION
ETHAMOLIN
* CYPROS

| | | |
|--|---------|--------------|
| | 50MG/ML | N19357 001 |
| | | DEC 22, 1988 |
| | 50MG/ML | N19357 001 |
| | | DEC 22, 1988 |

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21
TRIVORA-21
SEARLE

| | | |
|-----------|--|--------------|
| <u>AB</u> | 0.03MG, 0.04MG, 0.03MG; 0.05MG, 0.075MG | N74538 001 |
| | 0.125MG | DEC 18, 1997 |
| <u>AB</u> | 0.03MG, 0.04MG, 0.03MG; 0.05MG, 0.075MG, | N74538 001 |
| | 0.125MG | DEC 18, 1997 |

TABLET; ORAL-28
TRIVORA-28
SEARLE

| | | |
|-----------|--|--------------|
| <u>AB</u> | 0.03MG, 0.04MG, 0.03MG; 0.05MG, 0.075MG | N74538 002 |
| | 0.125MG | DEC 18, 1997 |
| <u>AB</u> | 0.03MG, 0.04MG, 0.03MG; 0.05MG, 0.075MG, | N74538 002 |
| | 0.125MG | DEC 18, 1997 |

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

| | | |
|---|----------------------|----------------|
| | OVCON-35 | |
| * | BRISTOL MYERS SQUIBB | 0.035MG; 0.4MG |
| + | WARNER CHILCOTT | 0.035MG; 0.4MG |
| | OVCON-50 | |
| @ | BRISTOL MYERS SQUIBB | 0.05MG; 1MG |
| @ | WARNER CHILCOTT | 0.05MG; 1MG |

TABLET; ORAL-28

| | | |
|---|----------------------|----------------|
| | OVCON-35 | |
| * | BRISTOL MYERS SQUIBB | 0.035MG; 0.4MG |
| + | WARNER CHILCOTT | 0.035MG; 0.4MG |
| | OVCON-50 | |
| @ | BRISTOL MYERS SQUIBB | 0.05MG; 1MG |
| @ | WARNER CHILCOTT | 0.05MG; 1MG |

ETODOLAC

CAPSULE; ORAL

| | | | |
|-----------|-----------------|-------|--------------|
| <u>AB</u> | <u>ETODOLAC</u> | 200MG | N75419 001 |
| | TORPHARM | | JUL 28, 2000 |
| <u>AB</u> | <u>ETODOLAC</u> | 300MG | N75419 002 |
| | TORPHARM | | JUL 28, 2000 |

TABLET; ORAL

| | | | |
|-----------|-----------------|-------|--------------|
| <u>AB</u> | <u>ETODOLAC</u> | 500MG | N75074 002 |
| | TARO PHARM INDS | | APR 25, 2000 |

TABLET, EXTENDED RELEASE; ORAL

| | | | |
|-----------|-----------------|-------|--------------|
| <u>AB</u> | <u>ETODOLAC</u> | 500MG | N75665 002 |
| | TEVA | | JUL 31, 2000 |
| <u>AB</u> | <u>ETODOLAC</u> | 600MG | N75665 001 |
| | TEVA | | JUL 31, 2000 |
| <u>AB</u> | WHITNEY PHARMS | 400MG | N75696 001 |
| | WHITNEY PHARMS | | JUL 31, 2000 |

LODINE XL

| | | | |
|-----------|------------------|-------|--------------|
| <u>AB</u> | <u>LODINE XL</u> | 400MG | N20584 001 |
| | WYETH AYERST | | OCT 25, 1996 |
| <u>AB</u> | <u>LODINE XL</u> | 500MG | N20584 003 |
| | WYETH AYERST | | JAN 20, 1998 |
| <u>AB</u> | <u>LODINE XL</u> | 600MG | N20584 002 |
| | WYETH AYERST | | OCT 25, 1996 |

ETODOLAC

TABLET, EXTENDED RELEASE; ORAL
LODINE XL
 * WYETH AYERST 400MG
 * 500MG
 * 600MG

N20584 001
 OCT 25, 1996
 N20584 003
 JAN 20, 1998
 N20584 002
 OCT 25, 1996

FENOLDOPAM MESYLATE

INJECTABLE; INJECTION
 CORLOPAM
 + ABBOTT EQ 10MG BASE/ML
 * ELAN PHARMA EQ 10MG BASE/ML

N19922 001
 SEP 23, 1997
 N19922 001
 SEP 23, 1997

FENTANYL CITRATE

INJECTABLE; INJECTION
SUBLIMAZE PRESERVATIVE FREE
 AP + AKORN MFG EQ 0.05MG BASE/ML
 AP * JANSSEN EQ 0.05MG BASE/ML

N16619 001
 N16619 001

FEXOFENADINE HYDROCHLORIDE

TABLET; ORAL
 ALLEGRA
 AVENTIS PHARMS 30MG
 60MG
 180MG
 +

N20872 001
 FEB 25, 2000
 N20872 002
 FEB 25, 2000
 N20872 004
 FEB 25, 2000

FLOXURIDINE

INJECTABLE; INJECTION
FLOXURIDINE
 AP BEDFORD 500MG/VIAL
 AP + ROCHE 500MG/VIAL

N75387 001
 APR 16, 2000
 N16929 001

FLOXURIDINE

INJECTABLE; INJECTION
FUDR
 * ROCHE 500MG/VIAL

N16929 001

FLUCONAZOLE

TABLET; ORAL
 DIFLUCAN
 PFIZER 150MG
 150MG

N20322 001
 JUN 30, 1994
 N19949 004
 JUN 30, 1994

FLUMAZENIL

INJECTABLE; INJECTION
 ROMAZICON
 + HLR 0.1MG/ML
 * ROCHE 0.1MG/ML

N20073 001
 DEC 20, 1991
 N20073 001
 DEC 20, 1991

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL
 AP GENSLA SICOR PHARMS 50MG/ML
 AP 50MG/ML

N40333 001
 JAN 27, 2000
 N40334 001
 FEB 25, 2000

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL
 SARAFEM
 LILLY
 +
 EQ 10MG BASE
 EQ 20MG BASE

N18936 007
 JUL 06, 2000
 N18936 008
 JUL 06, 2000

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN'2000 - AUG'2000

GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL
GLUCOVANCE

BRISTOL MYERS SQUIBB 2.5MG;500MG
5MG;500MG

N21178 002
JUL 31, 2000
N21178 003
JUL 31, 2000

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION
HALOPERIDOL DECANOATE

AO APOTEX EQ 50MG BASE/ML
AO EQ 100MG BASE/ML
AO KING PHARMS EQ 50MG BASE/ML
AO EQ 100MG BASE/ML

N75440 001
FEB 28, 2000
N75440 002
FEB 28, 2000
N75176 001
FEB 09, 2000
N75176 002
FEB 09, 2000

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATES AND GRAMICIDIN
EPHARM

0.025MG/ML; EQ 1.75MG BASE/ML;
10,000 UNITS/ML N62818 001
OCT 11, 1988
0.025MG/ML; EQ 1.75MG BASE/ML;
10,000 UNITS/ML N62818 001
OCT 11, 1988

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN LOCK FLUSH
STERIS

100 UNITS/ML
100 UNITS/ML

N17064 001
N17064 001

HEPARIN SODIUM
STERIS

AP 5,000 UNITS/ML
AP 10,000 UNITS/ML
AP 20,000 UNITS/ML
AP 40,000 UNITS/ML
@ 5,000 UNITS/ML
@ 10,000 UNITS/ML
@ 20,000 UNITS/ML
@ 40,000 UNITS/ML

N17064 003
N17064 004
N17064 005
N17064 006
N17064 003
N17064 004
N17064 005
N17064 006

GREPFLORACIN HYDROCHLORIDE

TABLET; ORAL
RAXAR

GLAXO WELLCOME

EQ 200MG BASE N20695 001
NOV 05, 1997
EQ 400MG BASE N20695 002
MAY 14, 1998
EQ 600MG BASE N20695 003
MAY 14, 1998
EQ 200MG BASE N20695 001
NOV 06, 1997
EQ 400MG BASE N20695 002
MAY 14, 1998
EQ 600MG BASE N20695 003
MAY 14, 1998

HISTRELIN ACETATE

INJECTABLE; INJECTION
SUPPRELIN
ROBERTS LABS

EQ 0.2MG BASE/ML
EQ 0.5MG BASE/ML
EQ 1MG BASE/ML

N19836 001
DEC 24, 1991
N19836 002
DEC 24, 1991
N19836 003
DEC 24, 1991
N19836 001
DEC 24, 1991
N19836 002
DEC 24, 1991
N19836 003
DEC 24, 1991

GRISEOFULVIN, ULTRAMICROCRYSTALLINE

TABLET; ORAL

GRIS-PEG
ALLEGAN HERBERT

125MG N50475 001
250MG N50475 002
125MG N50475 001
250MG N50475 002

AP
AB
AB
AB

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN'2000 - AUG'2000

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

DISC; TOPICAL

EPIFOAM
 @ SCHWARZ PHARMA
 PROCTOFOAM HC
 @ SCHWARZ PHARMA

1%;1%
 1%;1%

N86457 001
 N86195 001

> ADD >
 > ADD >
 > ADD >
 > ADD >

HYDROXYUREA

CAPSULE; ORAL
 HYDROXYUREA
 DURAMED

250MG

N75020 002
 JUN 26, 2000

TABLET; ORAL
 HYDROXYUREA
 +
 BARR

1GM

N75734 001
 AUG 29, 2000

HYDROCORTISONE BUTYRATE

CREAM; TOPICAL

LOCOID
 @ GALDERMA LABS
 @ YAMANOUCHI

0.1%
 0.1%

N18795 001
 JAN 07, 1983
 N18795 001
 JAN 07, 1983

LOCOID LIPOCREAM
 YAMANOUCHI

0.1%
 0.1%

N20769 001
 SEP 08, 1997
 N20769 001
 SEP 08, 1997

> DLT >
 > DLT >
 > ADD >
 > ADD >

INAMRINONE LACTATE

INJECTABLE; INJECTION
 AMRINONE
 BEDFORD

EQ 5MG BASE/ML

N75513 001
 MAY 09, 2000

AP

AMRINONE LACTATE
 BAXTER PHARM PROD

EQ 5MG BASE/ML

N75542 001
 MAY 10, 2000

AP

OINTMENT; TOPICAL

LOCOID
 @ GALDERMA LABS
 @ YAMANOUCHI

0.1%
 0.1%

N19106 001
 JUL 03, 1984
 N19106 001
 JUL 03, 1984

INSULIN ASPART RECOMBINANT

INJECTABLE; INJECTION
 NOVOLOG
 +
 NOVO NORDISK

100 UNITS/ML

N20986 001
 JUN 07, 2000

SOLUTION; TOPICAL

LOCOID
 @ GALDERMA LABS
 @ YAMANOUCHI

0.1%
 0.1%

N19819 001
 SEP 15, 1988
 N19819 001
 SEP 15, 1988

INSULIN GLARGINE

INJECTABLE; INJECTION
 LANTUS
 +
 AVENTIS PHARMS

100 UNITS/ML

N21081 001
 APR 20, 2000

HYDROCORTISONE VALERATE

CREAM; TOPICAL

HYDROCORTISONE VALERATE
 CLAY PARK

0.2%

N75666 001
 MAY 24, 2000

INSULIN LISPRO; INSULIN LISPRO PROTAMINE

INJECTABLE; INJECTION
 HUMALOG MIX 50/50
 +
 LILLY

50 UNITS/ML;50 UNITS/ML

N21018 001
 DEC 22, 1999

HUMALOG MIX 75/25
 +
 LILLY

25 UNITS/ML;75 UNITS/ML

N21017 001
 DEC 22, 1999

INSULIN LISPRO PROTAMINE

INJECTABLE; INJECTION
 HUMALOG MIX 50/50
 * LIQUID
 HUMALOG MIX 75/25
 * LIQUID

100 UNITS/ML
 100 UNITS/ML

N21018 001
 DEC 22, 1999
 N21017 001
 DEC 22, 1999

N11961 001

INULIN

INJECTABLE; INJECTION
 INULIN AND SODIUM CHLORIDE
 * CYROS
 + QUESTCOR PHARM

100MG/ML
 100MG/ML

N02282 001
 N02282 001

N12339 008
 N12339 008
 N86899 001
 N86899 001

IOPAMIDOL

INJECTABLE; INJECTION
 IOPAMIDOL-200
 AP COOK IMAGING
 IOPAMIDOL-250
 AP COOK IMAGING
 IOPAMIDOL-300
 AP COOK IMAGING
 IOPAMIDOL-370
 AP COOK IMAGING

41%
 51%
 61%
 76%

N74881 001
 JUL 28, 2000
 N74881 002
 JUL 28, 2000
 N74881 003
 JUL 28, 2000
 N74881 004
 JUL 28, 2000

N12339 007
 N12339 007

N74502 001
 JUN 27, 1995
 N74502 001
 JUN 27, 1995

IOTHALAMATE SODIUM, I-125

INJECTABLE; INJECTION
 GLOFIL-125
 * CYROS
 QUESTCOR PHARM

250-300 uCi/ML
 250-300 uCi/ML

N17279 001
 N17279 001

N11178 001
 N11178 001

IPRATROPIUM BROMIDE

SOLUTION; INHALATION
 IPRATROPIUM BROMIDE
 AN STERIPAK

0.02%

N75313 001
 FEB 07, 2000

N06327 002
 N06327 003
 N06327 002
 N06327 003

ISOCARBOXAZID

TABLET; ORAL
 MARPLAN
 + OXFORD PHARM

10MG

N11961 001

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION
 BRONKOSOL
 AN * SANOPI SYNTHELABO
 @
 ISOETHARINE HCL
 ROXANE
 AN *
 AN

1%
 1%
 1%
 1%

N12339 008
 N12339 008
 N86899 001
 N86899 001

ISOETHARINE MESYLATE

AEROSOL, METERED; INHALATION
 BRONKOMETER
 * SANOPI SYNTHELABO
 @

0.34MG/INH
 0.34MG/INH

N12339 007
 N12339 007

ISOFLURANE

LIQUID; INHALATION
 ISOFLURANE
 RHODIA

99.9%
 99.9%

N74502 001
 JUN 27, 1995
 N74502 001
 JUN 27, 1995

ISOPROTERENOL HYDROCHLORIDE

AEROSOL, METERED; INHALATION
 ISUPREL
 * SANOPI SYNTHELABO
 @

0.103MG/INH
 0.103MG/INH

N11178 001
 N11178 001

SOLUTION; INHALATION

ISUPREL
 * SANOPI SYNTHELABO
 *
 @
 @

0.5%
 1%
 0.5%
 1%

N06327 002
 N06327 003
 N06327 002
 N06327 003

ISOSORBIDE DINITRATE

TABLET, EXTENDED RELEASE; ORAL

AB * ISORDIA 40MG

AB * WYETH AVERST 40MG

AB * INWOOD LABS 40MG

AB * INWOOD LABS 40MG

N12882 001
JUL 29, 1988

N12882 001
JUL 29, 1988

N40009 001
DEC 30, 1998

N40009 001
DEC 30, 1998

ISOSORBIDE MONONITRATE

TABLET, EXTENDED RELEASE; ORAL

AB + IMDUR 120MG

AB + SCHERING 120MG

AB * DEXCEL LTD 60MG

AB * KREMERS URBAN 30MG

AB * KV PHARM 30MG

AB * KV PHARM 60MG

AB * ZENITH GOLDLINE 120MG

AB * ZENITH GOLDLINE 60MG

N20225 003
MAR 30, 1995

N20225 003
MAR 30, 1995

N75222 001
APR 17, 2000

N75155 002
JAN 13, 2000

N75155 003
AUG 04, 2000

N75395 001
MAR 16, 2000

N75395 002
MAR 16, 2000

N75395 003
MAR 16, 2000

N75448 001
JUN 19, 2000

KETOCONAZOLE

CREAM; TOPICAL

AB * NIZORAL 2%

AB * MCNEIL CONS 2%

AB * JANSSEN 2%

AB * MCNEIL CONS 2%

N19084 001
DEC 31, 1988

N19927 001
AUG 31, 1990

N19927 001
AUG 31, 1990

LACTULOSE

SOLUTION; ORAL

AB * DUPHALAC 10GM/15ML

AB * SOVAVY 10GM/15ML

N72372 001
MAR 22, 1989

N72372 001
MAR 22, 1989

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

AP * LEUCOVORIN CALCIUM PRESERVATIVE FREE EQ 10MG BASE/ML

AP * ABBOTT EQ 10MG BASE/ML

AP * BEDFORD EQ 10MG BASE/ML

AP * WELLCOVORIN EQ 350MG BASE/VIAL

AP * GLAXO WELLCOME EQ 100MG BASE/VIAL

N40147 001
JUN 25, 1997

N40147 001
JUN 25, 1997

N40347 001
APR 25, 2000

N40335 001
APR 20, 2000

N89834 001
JAN 23, 1989

N89834 001
JAN 23, 1989

KETOCONAZOLE

CREAM; TOPICAL

AB * KETOCONAZOLE 2%

AB * TEVA 2%

AB * NIZORAL 2%

AB * MCNEIL CONS 2%

N21088 001
MAR 03, 2000

> DLT >

> DLT >

> DLT >

> ADD >

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RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN' 2000 - AUG' 2000

1-29

LINEZOLID

TABLET; ORAL
ZYVOX

PHARMACIA AND UPJOHN 400MG
600MG

N21130 001
APR 18, 2000
N21130 002
APR 18, 2000

MELOXICAM

TABLET; ORAL
MOBIC

+ BOEHRINGER INGELHEIM 7.5MG

N20938 001
APR 13, 2000

MENOTROPINS (FSH; LH)

INJECTABLE; INJECTION
MENOTROPINS
@ FERRING

75 IU/VIAL; 75 IU/VIAL
150 IU/VIAL; 150 IU/VIAL

N73598 001
JAN 30, 1997
N73599 001
JAN 30, 1997

N74793 001
MAR 16, 2000
N74793 002
MAR 16, 2000

AB
REFRONEX
FERRING

75 IU/VIAL; 75 IU/VIAL
150 IU/VIAL; 150 IU/VIAL

N73598 001
JAN 30, 1997
N73599 001
JAN 30, 1997

MAGNESIUM SULFATE

INJECTABLE; INJECTION
MAGNESIUM SULFATE
ABBOTT

500MG/ML
500MG/ML
500MG/ML

N75151 001
APR 25, 2000
N19316 001
SEP 08, 1986
N19316 001
SEP 08, 1986

MEPERIDINE HYDROCHLORIDE

TABLET; ORAL
MEPERIDINE HCL
MALLINCKRODT

50MG
100MG

N40352 001
JUN 13, 2000
N40352 002
JUN 13, 2000

MEDROXYPROGESTERONE ACETATE

TABLET; ORAL
AMEN
AMARIN PHARMS
CARNRICK

10MG
10MG

N83242 001
N83242 001

MEPHENTERMINE SULFATE

INJECTABLE; INJECTION
WYAMINE SULFATE
* WYETH AYERST
@

EQ 30MG BASE/ML
EQ 30MG BASE/ML

N08248 001
N08248 001

MEGESTROL ACETATE

TABLET; ORAL
MEGESTROL ACETATE
PHARMACHEMIE

40MG
40MG

N74745 001
FEB 27, 1998
N74745 001
FEB 27, 1998

MESALAMINE

CAPSULE, EXTENDED RELEASE; ORAL
PENTASA
* ROBERTS LABS

250MG
250MG

N20049 001
MAY 10, 1993
N20049 001
MAY 10, 1993

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN' 2000 - AUG' 2000

1-30

MESALAMINE

SUPPOSITORY, RECTAL
 ROWASA
 * SOLVAY

500MG
 500MG

N19919 001
 DEC 18, 1990
 N19919 001
 DEC 18, 1990

> DLT >
 > DLT >
 > DLT >
 > DLT >

AB
 AB
 AB
 AB

TABLET, ORAL
METHIMAZOLE

5MG

10MG

5MG

10MG

5MG

10MG

N40320 001
 MAR 31, 2000
 N40320 002
 MAR 31, 2000
 N40350 001
 MAR 29, 2000
 N40350 002
 MAR 29, 2000
 N40320 001
 MAR 31, 2000
 N40320 002
 MAR 31, 2000

MESTRANOL, NORETHINDRONE

TABLET, ORAL-20
 NORINYL
 @ SEARLE
 @ WATSON LABS

0.1MG;2MG
 0.1MG;2MG

N13625 004
 N13625 004

> ADD >
 > ADD >
 > ADD >
 > ADD >

AB
 AB
 AB
 AB

5MG

10MG

5MG

10MG

N07517 002
 N07517 004
 N07517 002
 N07517 004

TABLET, ORAL-21
 NORINYL 1+50 21-DAY
 SEARLE
 WATSON LABS

0.05MG;1MG
 0.05MG;1MG

N13625 002
 N13625 002

> ADD >
 > ADD >

AB
 AB
 *

5MG
 10MG
 5MG
 10MG

METAPROTERENOL SULFATE

SOLUTION; INHALATION
 ALUPENT

AN * SOEHRINGER INGELHEIM 5%
 +
 AN PROMETA 5%
 NURO 5%

N17659 001
 N17659 001

> ADD >
 > ADD >
 > ADD >
 > ADD >

AB
 AB
 *

18MG
 36MG

N21121 001
 AUG 01, 2000
 N21121 002
 AUG 01, 2000

SYRUP; ORAL
METAPROTERENOL SULFATE
 NOVEX

10MG/5ML

N75235 001
 JAN 27, 2000

AB
 AB
 *

10MG
 10MG

N40306 001
 OCT 20, 1999
 N40306 001
 OCT 20, 1999

METHANTHILINE BROMIDE
 TABLET, ORAL
 BANTHINE
 * ROBERTS LABS
 + SHIRE LABS

50MG
 50MG

N07390 001
 N07390 001

BP
 BP

TABLET, ORAL
METHYLTESTOSTERONE
 ORETON METHYL
 SCHERING

10MG
 25MG

N75629 001
 MAY 09, 2000
 N75629 002
 MAY 09, 2000

10MG
 25MG

N03158 001
 N03158 002

METHYLPHENIDATE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
 CONCERTA
 + ALZA

18MG

36MG

N21121 001
 AUG 01, 2000
 N21121 002
 AUG 01, 2000

AB
 AB
 *

10MG
 10MG

N40306 001
 OCT 20, 1999
 N40306 001
 OCT 20, 1999

AB
 AB
 *

10MG
 20MG

N75629 001
 MAY 09, 2000
 N75629 002
 MAY 09, 2000

AB
 AB
 *

10MG
 20MG

N03158 001
 N03158 002

BP
 BP

10MG
 25MG

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN'2000 - AUG'2000

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METHYLTESTOSTERONE

TABLET, ORAL
~~ORION METHYL~~
 @ SCHERING

10MG
 25MG

N03158 001
 N03158 002

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION
MIDAZOLAM HCL
 ABBOTT

EQ 1MG BASE/ML

N75293 001
 JUN 20, 2000

EQ 1MG BASE/ML

N75409 002
 JUN 20, 2000

EQ 5MG BASE/ML

N75293 002
 JUN 20, 2000

EQ 5MG BASE/ML

N75409 001
 JUN 20, 2000

EQ 1MG BASE/ML

N75154 002
 JUN 20, 2000

EQ 5MG BASE/ML

N75154 001
 JUN 20, 2000

EQ 5MG BASE/ML

N75263 001
 JUN 26, 2000

EQ 1MG BASE/ML

N75324 001
 JUN 20, 2000

EQ 5MG BASE/ML

N75324 002
 JUN 20, 2000

EQ 1MG BASE/ML

N75247 002
 JUN 23, 2000

EQ 5MG BASE/ML

N75247 001
 JUN 23, 2000

EQ 5MG BASE/ML

N75249 001
 JUN 23, 2000

EQ 1MG BASE/ML

N75421 002
 JUN 20, 2000

EQ 5MG BASE/ML

N75421 001
 JUN 20, 2000

EQ 5MG BASE/ML

N75455 001
 JUN 20, 2000

EQ 1MG BASE/ML

N75243 001
 JUN 20, 2000

EQ 5MG BASE/ML

N75243 002
 JUN 20, 2000

EQ 1MG BASE/ML

N75396 001
 JUN 20, 2000

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION
MIDAZOLAM HCL
 FAULDING

EQ 5MG BASE/ML

N75396 002
 JUN 20, 2000

EQ 5MG BASE/ML

N75484 001
 JUN 20, 2000

EQ 5MG BASE/ML

N75481 001
 JUN 30, 2000

EQ 1MG BASE/ML

N75494 001
 JUN 30, 2000

EQ 5MG BASE/ML

N75494 002
 JUN 30, 2000

EQ 1MG BASE/ML

N18654 002
 MAY 26, 1987

EQ 5MG BASE/ML

N18654 001
 DEC 20, 1985

EQ 1MG BASE/ML

N18654 002
 MAY 26, 1987

EQ 5MG BASE/ML

N18654 001
 DEC 20, 1985

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL
 MINOCIN
 * LEDERLE

EQ 100MG BASE

N50649 002
 MAY 31, 1990

EQ 100MG BASE

N50649 002
 MAY 31, 1990

EQ 75MG BASE

N63065 002
 JUN 10, 1999

EQ 75MG BASE

N63065 002
 JUN 10, 1999

EQ 100MG BASE

N63065 001
 DEC 30, 1991

EQ 100MG BASE

N63065 001
 DEC 30, 1991

MONTELUKAST SODIUM

TABLET, CHEWABLE; ORAL
 SINGULAIR
 MERCK

EQ 4MG BASE

N20830 002
 MAR 03, 2000

| | | | | | | | | | |
|--|--------------------------------|------------|--------------|--|--|--|--|--|--|
| <u>MORPHINE SULFATE</u> | | | | | | | | | |
| TABLET, EXTENDED RELEASE; ORAL | | | | | | | | | |
| <u>MORPHINE SULFATE</u> | | | | | | | | | |
| AB ESI LEDERLE | 15MG | N75407 001 | JAN 28, 2000 | | | | | | |
| <u>NABUMETONE</u> | | | | | | | | | |
| TABLET; ORAL | | | | | | | | | |
| <u>NABUMETONE</u> | | | | | | | | | |
| AB COPLEY PHARM | 750MG | N75179 001 | JUN 06, 2000 | | | | | | |
| AB TEVA | 500MG | N75189 001 | MAY 26, 2000 | | | | | | |
| AB RELAFEN | 500MG | N19583 001 | DEC 24, 1991 | | | | | | |
| AB SMITHKLINE BEECHAM | 750MG | N19583 002 | DEC 24, 1991 | | | | | | |
| AB + | 500MG | N19583 001 | DEC 24, 1991 | | | | | | |
| AB + | 750MG | N19583 002 | DEC 24, 1991 | | | | | | |
| * + | 750MG | N19583 002 | DEC 24, 1991 | | | | | | |
| <u>NADOLOL</u> | | | | | | | | | |
| TABLET; ORAL | | | | | | | | | |
| <u>CORGARD</u> | | | | | | | | | |
| AB APOTHECON | 40MG | N18063 001 | | | | | | | |
| AB + | 40MG | N18063 001 | | | | | | | |
| <u>NAFCILLIN SODIUM</u> | | | | | | | | | |
| TABLET; ORAL | | | | | | | | | |
| <u>UNIPEN</u> | | | | | | | | | |
| * WYETH AYERST | EQ 500MG BASE | N50462 001 | | | | | | | |
| @ | EQ 500MG BASE | N50462 001 | | | | | | | |
| <u>NALMEFENE HYDROCHLORIDE</u> | | | | | | | | | |
| INJECTABLE; INJECTION | | | | | | | | | |
| REVEX | | | | | | | | | |
| + BAXTER PHARM PROD | EQ 0.1MG BASE/ML | N20459 001 | APR 17, 1995 | | | | | | |
| | | | | | | | | | |
| <u>NALMEFENE HYDROCHLORIDE</u> | | | | | | | | | |
| INJECTABLE; INJECTION | | | | | | | | | |
| REVEX | | | | | | | | | |
| + BAXTER PHARM PROD | EQ 1MG BASE/ML | N20459 002 | APR 17, 1995 | | | | | | |
| | | | | | | | | | |
| * ORNEDA | EQ 0.1MG BASE/ML | N20459 001 | APR 17, 1995 | | | | | | |
| * + | EQ 1MG BASE/ML | N20459 002 | APR 17, 1995 | | | | | | |
| <u>NALOXONE HYDROCHLORIDE, PENTAZOCINE HYDROCHLORIDE</u> | | | | | | | | | |
| TABLET; ORAL | | | | | | | | | |
| <u>PENTAZOCINE AND NALOXONE HYDROCHLORIDES</u> | | | | | | | | | |
| AB RANBAXY | EQ 0.5MG BASE; EQ 50MG BASE | N75523 001 | MAR 17, 2000 | | | | | | |
| <u>NALTREXONE HYDROCHLORIDE</u> | | | | | | | | | |
| TABLET; ORAL | | | | | | | | | |
| <u>NALTREXONE HCL</u> | | | | | | | | | |
| AB EON | 50MG | N75434 001 | MAR 08, 2000 | | | | | | |
| <u>NAPROXEN</u> | | | | | | | | | |
| TABLET, DELAYED RELEASE; ORAL | | | | | | | | | |
| <u>NAPROXEN</u> | | | | | | | | | |
| AB GENEVA PHARMS TECH | 375MG | N75061 001 | FEB 18, 1998 | | | | | | |
| AB | 500MG | N75061 002 | FEB 18, 1998 | | | | | | |
| AB INVAMED | 375MG | N75061 001 | FEB 18, 1998 | | | | | | |
| AB | 500MG | N75061 002 | FEB 18, 1998 | | | | | | |
| <u>NIACIN</u> | | | | | | | | | |
| TABLET; ORAL | | | | | | | | | |
| <u>NIACIN</u> | | | | | | | | | |
| AB GLOBAL PHARM | 500MG | N83115 001 | | | | | | | |
| @ IMPAX LABS | 500MG | N83115 001 | | | | | | | |

NIACIN

TABLET; ORAL

AA NIACOR
UPSHER SMITH

500MG

N40378 001
MAY 03, 2000

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL

AB NORTRIPTYLINE HCL
TARO

EQ 10MG BASE

N75520 004
MAY 08, 2000
N75520 003
MAY 08, 2000
N75520 001
MAY 08, 2000
N75520 002
MAY 08, 2000

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL

AB + ADALAT CC
BAYER

30MG

N20198 001
APR 21, 1993
N20198 001
APR 21, 1993

BC *

30MG

N75128 001
MAR 10, 2000

NIFEDIPINE

AB ELAN PHARM

30MG

> ADD >
> ADD >

AA SOLUTION; ORAL
NORTRIPTYLINE HCL
PHARM ASSOC

EQ 10MG BASE/5ML

N75606 001
AUG 28, 2000

NITROFURAZONE

CREAM; TOPICAL

AT FURACIN
* ROBERTS LABS
+ SHIRE LABS

0.2%
0.2%

N83789 001
N83789 001

TABLET; VAGINAL

NYSTATIN
ODYSSEY PHARMS

100,000 UNITS

N62615 001
OCT 17, 1985
N62615 001
OCT 17, 1985

OINTMENT; TOPICAL

AT FURACIN
* ROBERTS LABS
AT + SHIRE LABS

0.2%
0.2%

N05795 001
N05795 001

OCTREOTIDE ACETATE

INJECTABLE; INJECTION
SANDOSTATIN
NOVARTIS

EQ 0.2MG BASE/ML

N19667 004
JUN 12, 1991
N19667 005
JUN 12, 1991
N19667 004
JUN 12, 1991
N19667 005
JUN 12, 1991

NITROGLYCERIN

TABLET; SUBLINGUAL

NITROSTAT
PARKE DAVIS

0.3MG

N21134 001
MAY 01, 2000

0.4MG

N21134 002
MAY 01, 2000

0.6MG

N21134 003
MAY 01, 2000

+
+
SANDOSTATIN LAR
NOVARTIS

EQ 1MG BASE/ML

N21008 001
NOV 25, 1998
N21008 002
NOV 25, 1998
N21008 001
NOV 25, 1998

EQ 10MG BASE/VIAL

EQ 20MG BASE/VIAL

EQ 10MG BASE/VIAL

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OCTREOTIDE ACETATE

INJECTABLE; INJECTION
SANDOSTATIN LAR
+ NOVARTIS

EQ 20MG BASE/VIAL

N21008 002
NOV 25, 1998

OLANZAPINE

TABLET; ORAL
ZYPREXA
LILLY

2.5MG

N20592 001
SEP 30, 1996
N20592 004
SEP 30, 1996
N20592 005
SEP 09, 1997
N20592 001
SEP 30, 1996
N20592 004
SEP 30, 1996
N20592 005
SEP 09, 1997

10MG

15MG

2.5MG

10MG

15MG

TABLET, ORALLY DISINTEGRATING; ORAL

ZYPREXA ZYDIS

LILLY

5MG

10MG

15MG

20MG

N21086 001
APR 06, 2000
N21086 002
APR 06, 2000
N21086 003
APR 06, 2000
N21086 004
APR 06, 2000

ORLISTAT

CAPSULE; ORAL

XENICAL

+ HLR

* ROCHE

120MG

120MG

N20766 001
APR 23, 1999
N20766 001
APR 23, 1999

> ADD >
> ADD >
> DLT >
> DLT >

ORPHENADRINE CITRATE

TABLET, EXTENDED RELEASE; ORAL
ORPHENADRINE CITRATE

100MG

N40327 001
FEB 15, 2000
N40284 001
JUN 19, 1998
N40368 001
JUN 23, 2000
N40384 001
JUN 19, 1998

AB

GENEVA PHARMS TECH

100MG

IMPAX PHARM

100MG

INVAMISO

100MG

OXCARBAZEPINE

TABLET; ORAL
TRILEPTAL
NOVARTIS

150MG

300MG

600MG

N21014 001
JAN 14, 2000
N21014 002
JAN 14, 2000
N21014 003
JAN 14, 2000

+

OXYBUTYNIN CHLORIDE

TABLET, EXTENDED RELEASE; ORAL

5MG

N20897 001
DEC 16, 1998
N20897 001
DEC 16, 1998

AB

DITROPAN XL

5MG

+

OXYCODONE HYDROCHLORIDE

TABLET; ORAL

ROXICODONE

ROXANE

15MG

30MG

N21011 001
AUG 31, 2000
N21011 002
AUG 31, 2000

+

TABLET, EXTENDED RELEASE; ORAL

OXYCONTIN

BX * PURDUE PHARMA

10MG

N20553 001
DEC 12, 1995

OXYCODONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

OXYCONTIN
+ PURDUE PHARMA 10MG

+ 160MG

EX ROXICODONE
ROXANE

10MG

* 30MG

@ 10MG

@ 30MG

N20553 001
DEC 12, 1995
N20553 005
MAR 15, 2000

N20932 001
OCT 26, 1998
N20932 002
OCT 26, 1998

N20932 001
OCT 26, 1998
N20932 002
OCT 26, 1998

PANTOPRAZOLE SODIUM

TABLET, DELAYED RELEASE; ORAL

PROTONIX
+ WYETH AYERST EQ 40MG BASE

N20987 001
FEB 02, 2000

PEMOLINE

TABLET; ORAL

AB PEMOLINE
AMIDE PHARM

18.75MG

AB 37.5MG

AB 75MG

AB 18.75MG

AB 18.75MG

AB 37.5MG

AB 75MG

AB 18.75MG

AB 37.5MG

N75595 001
FEB 28, 2000
N75595 002
FEB 28, 2000
N75595 003
FEB 28, 2000
N75030 003
FEB 22, 2000
N75286 001
DEC 27, 1999
N75286 002
JUN 30, 1999
N75286 003
JUN 30, 1999
N75286 001
DEC 27, 1999
N75286 002
JUN 30, 1999

PEMOLINE

TABLET; ORAL

AB PEMOLINE
INVAMED

75MG

AB VINTAGE PHARMS

18.75MG

AB 37.5MG

AB 75MG

N75286 003
JUN 30, 1999
N75286 001
APR 19, 2000
N75286 002
APR 19, 2000
N75286 003
APR 19, 2000

TABLET, CHEWABLE; ORAL

AB CYLERT
+ ABBOTT

37.5MG

* 37.5MG

AB PEMOLINE
AMIDE PHARM

37.5MG

AB COPLEY PHARM

37.5MG

N17703 001
N17703 001

N75678 001
JUL 26, 2000
N75555 001
FEB 18, 2000

PENICILLIN G PROCAINE

INJECTABLE; INJECTION

> ADD >
> ADD >
> DLT >
> DLT >

AB AP
AP KING PHARMS

300,000 UNITS/ML

AB AP

AB WYETH AYERST

AB AP

AB AP

N60101 002
N60101 001
N60101 002
N60101 001

PENTAMIDINE ISETHIONATE

INJECTABLE; INJECTION

AB PENTACARINAT
ARMOUR PHARM

300MG/VIAL

@ 300MG/VIAL

N73447 001
APR 28, 1994
N73447 001
APR 28, 1994

PENTOXIFYLLINE

TABLET, EXTENDED RELEASE; ORAL

AB PENTOXIFYLLINE
IMPAX LABS

400MG

N75093 001
AUG 10, 1999

| | | | | | |
|--|--|--------------------|-------------------|---------------------|--|
| <u>PENTOXIFYLLINE</u> | | | | | |
| | TABLET, EXTENDED RELEASE; ORAL | | | | |
| | <u>PENTOXIFYLLINE</u> | | | | |
| <u>AB</u> | <u>IMPAX PHARM</u> | <u>400MG</u> | <u>N75093 001</u> | <u>AUG 10, 1999</u> | |
| > DLT > | | | | | |
| > DLT > | | | | | |
| > ADD > | | | | | |
| > ADD > | | | | | |
| > ADD > | | | | | |
| > ADD > | | | | | |
| <u>PERFLUOROPOLYMETHYLISOPROPYL ETHER, POLYTETRAFLUOROETHYLENE</u> | | | | | |
| | PASTE; TOPICAL | | | | |
| | SKIN EXPOSURE REDUCTION PASTE AGAINST CHEMICAL WARFARE | | | | |
| | AGENTS | | | | |
| + | US ARMY | 50%; 50% | <u>N21084 001</u> | <u>FEB 17, 2000</u> | |
| <u>PERINDOPRIL ERBUMINE</u> | | | | | |
| | TABLET; ORAL | | | | |
| | <u>ACEON</u> | 2MG | <u>N20184 001</u> | <u>DEC 30, 1993</u> | |
| | <u>SOLVAY</u> | 4MG | <u>N20184 002</u> | <u>DEC 30, 1993</u> | |
| | | 8MG | <u>N20184 003</u> | <u>DEC 30, 1993</u> | |
| | | 2MG | <u>N20184 001</u> | <u>DEC 30, 1993</u> | |
| | | 4MG | <u>N20184 002</u> | <u>DEC 30, 1993</u> | |
| | | 8MG | <u>N20184 003</u> | <u>DEC 30, 1993</u> | |
| + | | | | | |
| <u>PHENDIMETRAZINE TARTRATE</u> | | | | | |
| | TABLET; ORAL | | | | |
| | <u>BONTRIL PDM</u> | 35MG | <u>N85272 001</u> | | |
| <u>AA</u> | <u>AMARIN PHARMS</u> | <u>35MG</u> | <u>N85272 001</u> | | |
| <u>AA</u> | <u>CARRICK</u> | | | | |
| <u>PIROXICAM</u> | | | | | |
| | CAPSULE; ORAL | | | | |
| | <u>PIROXICAM</u> | | | | |
| | <u>ROXANE</u> | 10MG | <u>N73651 001</u> | <u>FEB 26, 1993</u> | |
| > DLT > | | | | | |
| > DLT > | | | | | |
| <u>PIROXICAM</u> | | | | | |
| | CAPSULE; ORAL | | | | |
| | <u>PIROXICAM</u> | | | | |
| | <u>ROXANE</u> | 20MG | <u>N73651 002</u> | <u>FEB 26, 1993</u> | |
| | | 10MG | <u>N73651 001</u> | <u>FEB 26, 1993</u> | |
| | | 20MG | <u>N73651 002</u> | <u>FEB 26, 1993</u> | |
| <u>POTASSIUM CHLORIDE</u> | | | | | |
| | TABLET, EXTENDED RELEASE; ORAL | | | | |
| | <u>K-DUR 10</u> | | | | |
| | + <u>KEY PHARMS</u> | 10MEQ | <u>N19439 002</u> | <u>JUN 13, 1986</u> | |
| > ADD > | | | | | |
| > ADD > | | | | | |
| > DLT > | | | | | |
| > DLT > | | | | | |
| > ADD > | | | | | |
| > ADD > | | | | | |
| <u>PREDNISOLONE</u> | | | | | |
| | SYRUP; ORAL | | | | |
| | <u>PREDNISOLONE</u> | | | | |
| | <u>COPLEY PHARM</u> | 15MG/5ML | <u>N40322 001</u> | <u>JAN 19, 2000</u> | |
| <u>AA</u> | | | | | |
| <u>PREDNISOLONE</u> | | | | | |
| | TABLET; ORAL | | | | |
| | <u>PREDNISOLONE</u> | | | | |
| | <u>GLOBAL PHARM</u> | 5MG | <u>N80780 001</u> | | |
| <u>BX</u> | <u>IMPAX LABS</u> | 5MG | <u>N80780 001</u> | | |
| <u>BX</u> | <u>PHOENIX LABS NY</u> | 5MG | <u>N80322 001</u> | | |
| | | 5MG | <u>N80322 001</u> | | |
| <u>PREDNISOLONE SODIUM PHOSPHATE</u> | | | | | |
| | SOLUTION/DROPS; OPHTHALMIC | | | | |
| | <u>PREDNISOLONE SODIUM PHOSPHATE</u> | | | | |
| | <u>ALCON UNIVERSAL</u> | EQ 0.11% PHOSPHATE | <u>N81043 001</u> | <u>OCT 24, 1991</u> | |
| <u>AT</u> | | | <u>N81044 001</u> | <u>OCT 24, 1991</u> | |
| <u>AT</u> | | EQ 0.9% PHOSPHATE | | | |

| | | | |
|--|---|--------------------------------|-----------------------------------|
| <u>PREDNISOLONE SODIUM PHOSPHATE</u> | | | |
| SOLUTION/DROPS; OPHTHALMIC | | | |
| <u>AT</u> | <u>PREDNISOLONE SODIUM PHOSPHATE</u> | <u>EQ 0.11% PHOSPHATE</u> | <u>N81043 001</u> OCT 24, 1991 |
| <u>AT</u> | <u>STERIS</u> | | <u>N81044 001</u> OCT 24, 1991 |
| <u>PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM</u> | | | |
| SOLUTION/DROPS; OPHTHALMIC | | | |
| <u>AT</u> | <u>SULFACETAMIDE SODIUM AND PREDNISOLONE SODIUM PHOSPHATE</u> | <u>EQ 0.23% PHOSPHATE; 10%</u> | <u>N73630 001</u> MAY 27, 1993 |
| <u>AT</u> | <u>ALCON UNIVERSAL</u> | | <u>N73630 001</u> MAY 27, 1993 |
| <u>AT</u> | <u>STERIS</u> | <u>EQ 0.23% PHOSPHATE; 10%</u> | <u>N73630 001</u> MAY 27, 1993 |
| <u>PREDNISON</u> | | | |
| SYRUP; ORAL | | | |
| <u>+</u> | <u>LIQUID PRED</u> | | <u>N87611 002</u> SEP 07, 1982 |
| <u>@</u> | <u>MURO</u> | <u>5MG/5ML</u> | <u>N87611 002</u> SEP 07, 1982 |
| TABLET; ORAL | | | |
| <u>AB</u> | <u>EREDNICEN-M</u> | <u>5MG</u> | <u>N84655 001</u> |
| <u>BX</u> | <u>CENT PHARMS</u> | <u>5MG</u> | <u>N84655 001</u> |
| <u>BX</u> | <u>SCHWARZ PHARMA</u> | <u>5MG</u> | <u>N80321 001</u> |
| <u>@</u> | <u>PREDNISON</u> | <u>20MG</u> | <u>N83807 001</u> |
| <u>@</u> | <u>PHOENIX LABS NY</u> | <u>5MG</u> | <u>N80321 001</u> |
| | | <u>20MG</u> | <u>N83807 001</u> |
| <u>PROCHLORPERAZINE</u> | | | |
| <u>AB</u> | <u>SUPPOSITORY; RECTAL</u> | <u>25MG</u> | <u>N40246 001</u> JUN 28, 2000 |
| | <u>COMPRO</u> | | |
| | <u>FADDOCK</u> | | |
| <u>PROGESTERONE</u> | | | |
| CAPSULE; ORAL | | | |
| | <u>PROMETRIUM</u> | <u>100MG</u> | <u>N19781 001</u> MAY 14, 1998 |
| | <u>SCHERING PLOUGH</u> | <u>200MG</u> | <u>N19781 002</u> OCT 15, 1999 |
| <u>*</u> | | <u>300MG</u> | <u>N19781 003</u> OCT 15, 1999 |
| <u>+</u> | <u>UNIMED PHARMS</u> | <u>100MG</u> | <u>N19781 001</u> MAY 14, 1998 |
| <u>@</u> | | <u>200MG</u> | <u>N19781 002</u> OCT 15, 1999 |
| | | <u>300MG</u> | <u>N19781 003</u> OCT 15, 1999 |
| <u>PROMETHAZINE HYDROCHLORIDE</u> | | | |
| INJECTABLE; INJECTION | | | |
| <u>AP</u> | <u>PROMETHAZINE HCL</u> | <u>25MG/ML</u> | <u>N40372 001</u> JUN 08, 2000 |
| <u>AP</u> | <u>ABBOTT</u> | <u>50MG/ML</u> | <u>N40372 002</u> JUN 08, 2000 |
| <u>PROPANTHELINE BROMIDE</u> | | | |
| TABLET; ORAL | | | |
| <u>BP</u> | <u>PRO-BANTHINE</u> | <u>7.5MG</u> | <u>N08732 001</u> |
| <u>BP</u> | <u>ROBERTS LABS</u> | <u>15MG</u> | <u>N08732 002</u> |
| <u>BP</u> | <u>SHIRE LABS</u> | <u>7.5MG</u> | <u>N08732 003</u> |
| <u>BP</u> | | <u>15MG</u> | <u>N08732 002</u> |
| <u>PROPARACAINE HYDROCHLORIDE</u> | | | |
| SOLUTION; OPHTHALMIC | | | |
| <u>AT</u> | <u>PROPARACAINE HCL</u> | <u>0.5%</u> | <u>N40277 001</u> MAR 16, 2000 |
| | <u>TAYLOR PHARMA</u> | | |

PROPRANOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

INDERAL

+ WYETH AYERST

* PROPRANOLOL HCL

BEDFORD

> ADD >
> DLT >
> ADD >
> ADD >
> ADD >

1MG/ML
1MG/ML

1MG/ML

N16419 001
N16419 001

N75792 001
AUG 29, 2000

PROTOKYLOL HYDROCHLORIDE

TABLET; ORAL

VENTAIRE

@ AVENTIS PHARMS

* HOECHST MARION ROSS

2MG
2MG

N83459 001
N83459 001

QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

@ PHARMAVITE

200MG
200MG

N84627 001
N84627 001

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

RANITIDINE

@ RANBAXY

EQ 150MG BASE

EQ 300MG BASE

N75439 001
APR 19, 2000
N75439 002
APR 19, 2000

RESERPINE

TABLET; ORAL

RESERPINE

@ GLOBAL PHARM

* IMPAX LABS

0.1MG
0.25MG
0.1MG
0.25MG

N09627 001
N09627 002
N09627 001
N09627 002

> ADD >
> ADD >
> ADD >
> ADD >

RIVASTIGMINE TARTRATE

CAPSULE; ORAL

EXELON

NOVARTIS

EQ 1.5MG BASE

EQ 3MG BASE

EQ 4.5MG BASE

EQ 6MG BASE

N20823 003
APR 21, 2000
N20823 004
APR 21, 2000
N20823 005
APR 21, 2000
N20823 006
APR 21, 2000

+

SOLUTION; ORAL

EXELON

+ NOVARTIS

EQ 2MG BASE/ML

N21025 001
APR 21, 2000

SELENIUM SULFIDE

LOTION/SHAMPOO; TOPICAL

SELENIUM SULFIDE

@ ZENITH GOLDLINE

2.5%
2.5%

N85777 001
N85777 001

SEVELAMER HYDROCHLORIDE

TABLET; ORAL

RENAGEL

@ GELTEX

400MG

800MG

N21179 001
JUL 12, 2000
N21179 002
JUL 12, 2000

SIROLIMUS

TABLET; ORAL

RAPAMUNE

+ WYETH AYERST

1MG

N21110 001
AUG 25, 2000

SODIUM FLUORIDE, F-18

INJECTABLE; INTRAVENOUS

FLUORINE F-18

@ NYCOMED AMERSHAM

2mCi/ML

N17042 001

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN'2000 - AUG'2000

SOMATROPIN RECOMBINANT

INJECTABLE; INJECTION
NORDITROPIN
NOVO NORDISK

5MG/1.5ML
10MG/1.5ML
15MG/1.5ML

N21148 001
JUN 20, 2000
N21148 002
JUN 20, 2000
N21148 003
JUN 20, 2000

AB
AB

SOTALOL HYDROCHLORIDE

TABLET; ORAL
SOTALOL HCL
GENPHARM

80MG
120MG
160MG
240MG
80MG
120MG
160MG
240MG
80MG
120MG
160MG
240MG

N75237 001
MAY 01, 2000
N75237 002
MAY 01, 2000
N75237 003
MAY 01, 2000
N75237 004
MAY 01, 2000
N75429 001
MAY 01, 2000
N75429 002
MAY 01, 2000
N75429 003
MAY 01, 2000
N75429 004
MAY 01, 2000
N75238 001
JUL 13, 2000
N75238 002
JUL 13, 2000
N75238 003
JUL 13, 2000
N75238 004
JUL 13, 2000

SOTALOL HYDROCHLORIDE

TABLET; ORAL
BETAPACE
BERLEX LABS

80MG
120MG
160MG
240MG
80MG
120MG
160MG
240MG

N19865 001
OCT 30, 1992
N19865 005
APR 20, 1994
N19865 002
OCT 30, 1992
N19865 003
OCT 30, 1992
N19865 001
OCT 30, 1992
N19865 005
APR 20, 1994
N19865 002
OCT 30, 1992
N19865 003
OCT 30, 1992

AB
AB
AB
AB

WATSON LABS

BETAPACE AF
BERLEX LABS

80MG
120MG
160MG

N21151 001
FEB 22, 2000
N21151 002
FEB 22, 2000
N21151 003
FEB 22, 2000

AB
AB
AB

INJECTABLE; INJECTION

METASTRON
NYCOMED AMERSHAM

N20134 001
JUN 18, 1993
N20134 001
JUN 18, 1993

1mCi/ML
1mCi/ML

SOTALOL HCL

EON

80MG
120MG
160MG
240MG

N75366 001
MAY 01, 2000
N75366 002
MAY 01, 2000
N75366 003
MAY 01, 2000
N75366 004
MAY 01, 2000

AB
AB
AB
AB

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

OCUSULF-10
MIZA PHARMS USA
OPTOPICS
OCUSULF-30
MIZA PHARMS USA
OPTOPICS

N80660 001
N80660 001
N80660 002
N80660 002

10%
10%
30%
30%

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

SULFACETAMIDE SODIUM

AT ALCON UNIVERSAL 10%

AT STERIS 10%

N89560 001
OCT 18, 1988
N89560 001
OCT 18, 1988

AB CAPSULE; ORAL
TERAZOSIN HCL

EQ 1MG BASE

N75667 001
JUL 28, 2000

N89560 001
OCT 18, 1988

AB INVAMED

EQ 2MG BASE

N75667 002
JUL 28, 2000

N89560 001
OCT 18, 1988

AB INVAMED

EQ 5MG BASE

N75667 003
JUL 28, 2000

TACRINE HYDROCHLORIDE

CAPSULE; ORAL
COGNEX

FIRST HORIZON

EQ 10MG BASE

N20070 001
SEP 09, 1993

EQ 20MG BASE

N20070 002
SEP 09, 1993

EQ 30MG BASE

N20070 003
SEP 09, 1993

EQ 40MG BASE

N20070 004
SEP 09, 1993

+

PARKE DAVIS PHARMS

EQ 10MG BASE

N20070 001
SEP 09, 1993

EQ 20MG BASE

N20070 002
SEP 09, 1993

EQ 30MG BASE

N20070 003
SEP 09, 1993

EQ 40MG BASE

N20070 004
SEP 09, 1993

*

TAMOXIFEN CITRATE

TABLET; ORAL

TAMOXIFEN CITRATE

@ MYLAN

EQ 10MG BASE

N74732 001
JUN 26, 2000

@ PHARMACHEMIE

EQ 10MG BASE

N74539 001
MAY 31, 2000

TELMISARTAN

TABLET; ORAL

MICARDIS

+ BOEHRINGER INGELHEIM 20MG

N20850 003
APR 04, 2000

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

TERAZOSIN HCL

INVAMED

EQ 1MG BASE

N75667 001
JUL 28, 2000

EQ 2MG BASE

N75667 002
JUL 28, 2000

EQ 5MG BASE

N75667 003
JUL 28, 2000

EQ 10MG BASE

N75667 004
JUL 28, 2000

EQ 1MG BASE

MYLAN

N75140 002
FEB 11, 2000

EQ 2MG BASE

N75140 003
FEB 11, 2000

EQ 5MG BASE

N75140 001
FEB 11, 2000

EQ 10MG BASE

N75140 004
FEB 11, 2000

TABLET; ORAL

TERAZOSIN HCL

INVAMED

EQ 1MG BASE

N74657 001
APR 28, 2000

EQ 2MG BASE

N74657 002
APR 28, 2000

EQ 5MG BASE

N74657 003
APR 28, 2000

EQ 10MG BASE

N74657 004
APR 28, 2000

AB NOVOPHARM

EQ 1MG BASE

N74446 001
MAY 18, 2000

EQ 2MG BASE

N74446 002
MAY 18, 2000

EQ 5MG BASE

N74446 003
MAY 18, 2000

EQ 10MG BASE

N74446 004
MAY 18, 2000

ZENITH GOLDLINE

EQ 1MG BASE

N74530 001
APR 21, 2000

EQ 2MG BASE

N74530 002
APR 21, 2000

EQ 5MG BASE

N74530 003
APR 21, 2000

EQ 10MG BASE

N74530 004
APR 21, 2000

| TESTOSTERONE | FILM, EXTENDED RELEASE; TRANSDERMAL | N20489 002 MAY 02, 1997 | TICLOPIDINE HYDROCHLORIDE | N20484 001 JUL 14, 2000 |
|---------------------------------|-------------------------------------|----------------------------|---------------------------|----------------------------|
| BX * THERATECH | ANDRODERM | N20489 001 MAY 02, 1997 | TABLET; ORAL | |
| | 5MG/24HR | N20489 002 MAY 02, 1997 | TICLOPIDINE HCL | N75309 001 APR 26, 2000 |
| | 2.5MG/24HR | N20489 001 SEP 29, 1995 | AB DANBURY PHARMA | 250MG |
| BX + WATSON LABS | 5MG/24HR | N20489 002 MAY 02, 1997 | TINZAPARIN SODIUM | |
| | 2.5MG/24HR | N20489 001 SEP 29, 1995 | INJECTABLE; INJECTION | |
| | | | INNOHEP | |
| | | | + DUPONT PHARMA | 20,000 IU/ML |
| GEL; TOPICAL | | | | |
| ANDROGEL | | N21015 001 FEB 28, 2000 | TIZANIDINE HYDROCHLORIDE | |
| + UNIMED PHARMS | 1% | | TABLET; ORAL | |
| | | | ZANAFLEX | |
| | | | ELAN PHARMA | EQ 2MG BASE |
| THEOPHYLLINE | | | | N20397 002 FEB 04, 2000 |
| CAPSULE, EXTENDED RELEASE; ORAL | | | | |
| SLO-PHYLLIN | | N85206 001 MAY 24, 1982 | TOLBUTAMIDE | |
| @ AVENTIS PHARM PROD | 60MG | N85203 001 MAY 24, 1982 | TABLET; ORAL | |
| | | N85205 001 MAY 24, 1982 | TOLBUTAMIDE | 500MG |
| | | N85203 001 MAY 24, 1982 | CHLSEA LABS | 500MG |
| BC RHONE-POULENC RORER | 125MG | N85205 001 MAY 24, 1982 | AB + EON | 500MG |
| | | N85205 001 MAY 24, 1982 | AB | 500MG |
| BC | 250MG | N85206 001 MAY 24, 1982 | TRETINOIN | N86109 001 |
| | | | CREAM; TOPICAL | N86109 001 |
| | | | RENOVA | N12678 001 |
| | | | + JOHNSON AND JOHNSON | N12678 001 |
| | | | | 0.02% |
| THIAMINE HYDROCHLORIDE | | | | |
| INJECTABLE; INJECTION | | | | |
| BETALIN S | | N80853 001 | GEL; TOPICAL | |
| * HILLY | 100MG/ML | N80853 001 | RETIN-A | N17579 002 |
| | 100MG/ML | N80556 001 | + JOHNSON AND JOHNSON | N17579 002 |
| THIAMINE HCL | | N80556 001 | BT | |
| AM PHARM PARTNERS | 100MG/ML | N80556 001 | TRETINOIN | N75529 001 |
| AP | 100MG/ML | | SPEAR PHARMS | FEB 22, 2000 |
| AP | | | | |
| AP | | | | |

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

FLUTEX
 * ZENITH GOLDLINE
 @
 @
 @
TRIATEX
 * ZENITH GOLDLINE
 @
 @
 @

0.025%
 0.1%
 0.5%
 0.025%
 0.1%
 0.5%
 0.025%
 0.1%
 0.5%
 0.025%
 0.1%
 0.5%
 0.025%
 0.1%
 0.5%

> DLT >
 > ADD >
 > DLT >
 > ADD >

N85539 001
 N85539 002
 N85539 003
 N85539 001
 N85539 002
 N85539 003
 N87430 001
 NOV 01, 1988
 N87429 001
 NOV 01, 1988
 N87428 001
 NOV 01, 1988
 N87430 001
 NOV 01, 1988
 N87429 001
 NOV 01, 1988
 N87428 001
 NOV 01, 1988

SPRAY, METERED; NASAL
 TRI-NASAL
 + MURO
 0.05MG/SPRAY

N855691 003
 N85691 003
 N85691 002
 N85691 002
 N87356 001
 N87356 001
 N87357 001
 N87385 001
 N87385 001

ONIMENT; TOPICAL

ARISTOCORT A
 * FUJISAWA HEALTHCARE
FLUTEX
 * ZENITH GOLDLINE
 @
 @
 @

0.5%
 0.5%
 0.025%
 0.1%
 0.5%
 0.025%
 0.1%
 0.5%

N80745 003
 N80745 003
 N87375 001
 NOV 01, 1988
 N87377 001
 NOV 01, 1988
 N87376 001
 NOV 01, 1988
 N87375 001
 NOV 01, 1988
 N87377 001
 NOV 01, 1988
 N87376 001
 NOV 01, 1988

> DLT >
 > ADD >
 > DLT >
 > ADD >

N87612 001
 NOV 19, 1982
 N87613 001
 NOV 19, 1982
 N87328 001
 NOV 19, 1982
 N87614 001
 NOV 19, 1982
 N87612 001
 NOV 19, 1982
 N87613 001
 NOV 19, 1982
 N87328 001
 NOV 19, 1982
 N87614 001
 NOV 19, 1982

KENALOG
 * APOTHECON

0.025%
 0.025%
 0.1%
 0.1%
 0.5%
 0.025%
 0.025%
 0.1%
 0.1%
 0.5%

N11600 003
 N11600 003
 N11600 001
 N11600 001
 N85691 001
 N85691 001

> DLT >
 > ADD >

N40337 002
 FEB 16, 2000

TRIHYPHENIDYL HYDROCHLORIDE

TABLET; ORAL
TRIHYPHENIDYL HCL
 WEST WARD

AA N40337 001
 FEB 16, 2000

5MG

TRIMETHOPRIM HYDROCHLORIDE

SOLUTION; ORAL
 PRIMSOL
 ASCENT PEDS

+ N74374 001
 JUN 23, 1995
 N74374 001
 JUN 23, 1995
 N74973 001
 JAN 24, 2000

EQ 25MG BASE/5ML
 EQ 25MG BASE/5ML
 EQ 50MG BASE/5ML

200MG
 300MG
 400MG

AB REZULIN
 PARKE DAVIS PHARMS

N20720 001
 JAN 29, 1997
 N20720 003
 AUG 04, 1997
 N20720 002
 JAN 29, 1997
 N20720 001
 JAN 29, 1997
 N20720 003
 AUG 04, 1997
 N20720 002
 JAN 29, 1997

TRIMETREXATE GLUCURONATE

INJECTABLE; INJECTION
 NEUTREXIN
 + MEDIMUNE ONCOLOGY
 * US BIOSCIENCE

N20326 001
 DEC 17, 1993
 N20326 001
 DEC 17, 1993

EQ 25MG BASE/VIAL
 EQ 25MG BASE/VIAL

TROPICAMIDE

SOLUTION/DROPS; OPHTHALMIC

TRIPTORELIN PAMOATE

INJECTABLE; INJECTION
 TRELSTAR DEPOT
 + DEBIO RECHERCHE

N20715 001
 JUN 15, 2000

EQ 3.75MG BASE/VIAL

AT ALCON UNIVERSAL 1%
 AT MIZA PHARMS USA 0.5%
 AT MIZA PHARMS USA 1%
 AT OPTOPICS 0.5%
 AT OPTOPICS 1%
 AT STERIS 1%

N89172 001
 DEC 28, 1990
 N87636 001
 JUL 30, 1982
 N87637 001
 AUG 09, 1982
 N87636 001
 JUL 30, 1982
 N87637 001
 AUG 09, 1982
 N89172 001
 DEC 28, 1990

TROGLITAZONE

TABLET; ORAL
 FRELAY
 SANKYO

N20719 001
 JAN 29, 1997
 N20719 003
 AUG 04, 1997
 N20719 002
 JAN 29, 1997

200MG
 300MG
 400MG

UNOPROSTONE ISOPROPYL

SOLUTION/DROPS; OPHTHALMIC
 RESCULA
 + CIBA

N21214 001
 AUG 03, 2000

0.15%

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN' 2000 - AUG' 2000

1-44

| Product Name | Strength | Approval Date | Manufacturer | Approval Number |
|--------------------------------|-----------------------------|---------------|--------------|-----------------|
| <u>URSODIOL</u> | | | | |
| CAPSULE; ORAL | | | | |
| <u>ACTIGALL</u> | | | | |
| <u>AB</u> + NOVARTIS | <u>300MG</u> | N19594 002 | | N21119 001 |
| | <u>300MG</u> | DEC 31, 1987 | | APR 12, 2000 |
| | | N19594 002 | | |
| | | DEC 31, 1987 | | |
| <u>URSODIOL</u> | | | | |
| <u>AB</u> AMIDE PHARM | <u>300MG</u> | N75517 001 | | |
| | | MAR 14, 2000 | | |
| <u>AB</u> COPLEY PHARM | <u>300MG</u> | N75592 001 | | |
| | | MAY 25, 2000 | | |
| TABLET; ORAL | | | | |
| <u>URSO</u> | | | | |
| * <u>AXCAN</u> | <u>250MG</u> | N20675 001 | | |
| + AXCAN SCANDIPHARM | <u>250MG</u> | DEC 10, 1997 | | |
| | | N20675 001 | | |
| | | DEC 10, 1997 | | |
| <u>VECURONIUM BROMIDE</u> | | | | |
| INJECTABLE; INJECTION | | | | |
| <u>VECURONIUM BROMIDE</u> | | | | |
| <u>AP</u> BEDFORD | <u>10MG/VIAL</u> | N75549 001 | | |
| | | JUN 13, 2000 | | |
| <u>AP</u> | <u>20MG/VIAL</u> | N75549 002 | | |
| | | JUN 13, 2000 | | |
| <u>VERAPAMIL HYDROCHLORIDE</u> | | | | |
| TABLET, EXTENDED RELEASE; ORAL | | | | |
| <u>COVERA-HS</u> | | | | |
| <u>BC</u> SEARLE | <u>180MG</u> | N20552 001 | | |
| | | FEB 26, 1996 | | |
| <u>BC</u> + | <u>180MG</u> | N20552 001 | | |
| | | FEB 26, 1996 | | |
| <u>BC</u> | <u>240MG</u> | N20552 002 | | |
| | | FEB 26, 1996 | | |
| <u>BC</u> + | <u>240MG</u> | N20552 002 | | |
| | | FEB 26, 1996 | | |
| <u>VERTEPORFIN</u> | | | | |
| INJECTABLE; INJECTION | | | | |
| <u>VISUDYNE</u> | | | | |
| + QLT | <u>15MG/VIAL</u> | | | |
| <u>VITAMIN A</u> | | | | |
| CAPSULE; ORAL | | | | |
| <u>VITAMIN A</u> | | | | |
| GLOBAL PHARM | | | | |
| @ IMPAX LABS | | | | |
| <u>AA</u> | <u>50,000 USP UNITS</u> | N80952 001 | | |
| | <u>50,000 USP UNITS</u> | N80952 001 | | |
| <u>VITAMIN A PALMITATE</u> | | | | |
| CAPSULE; ORAL | | | | |
| <u>VITAMIN A</u> | | | | |
| GLOBAL PHARM | | | | |
| @ IMPAX LABS | | | | |
| <u>AA</u> | <u>EQ 50,000 UNITS BASE</u> | N80953 001 | | |
| | <u>EQ 50,000 UNITS BASE</u> | N80955 001 | | |
| | <u>EQ 50,000 UNITS BASE</u> | N80953 001 | | |
| | <u>EQ 50,000 UNITS BASE</u> | N80955 001 | | |
| <u>WARFARIN SODIUM</u> | | | | |
| TABLET; ORAL | | | | |
| <u>WARFARIN SODIUM</u> | | | | |
| INVAMED | | | | |
| <u>AB</u> | <u>3MG</u> | N40196 008 | | |
| | | JUL 26, 2000 | | |
| <u>AB</u> | <u>6MG</u> | N40196 009 | | |
| | | JUL 26, 2000 | | |
| <u>ZAFIRLUKAST</u> | | | | |
| TABLET; ORAL | | | | |
| ACCOLATE | | | | |
| ASTRAZENECA UK | | | | |
| > <u>ADD</u> > | <u>10MG</u> | N20547 003 | | |
| > <u>ADD</u> > | | SEP 17, 1999 | | |
| <u>ZOLMITRIPTAN</u> | | | | |
| TABLET; ORAL | | | | |
| ZOMIG | | | | |
| ASTRAZENECA PHARMS | | | | |
| | <u>2.5MG</u> | N20768 001 | | |
| | | NOV 25, 1997 | | |

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN'2000 - AUG'2000

ZOLMITRIPTAN

TABLET; ORAL

ZOMIG
+ ASTRAZENECA PHARMS 5MG

2.5MG

N20768 002
NOV 25, 1997

ZENECA

N20768 001
NOV 25, 1997

5MG

N20768 002
NOV 25, 1997

*

ZONISAMIDE

CAPSULE; ORAL

ZONEGRAN
+ DAINIPPON 100MG

N20789 001
MAR 27, 2000

OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN'2000 - AUG'2000

IBUPROFEN, PSEUDOEPHEDRINE HYDROCHLORIDE

> ADD >
 > ADD >
 > ADD >
 > ADD >

SUSPENSION; ORAL
 CHILDREN'S MOTRIN COLD
 + MCNEIL CONS
 100MG/5ML;15MG/5ML
 N21128 001
 AUG 01, 2000

LOPERAMIDE HYDROCHLORIDE

TABLET; ORAL
 LOPERAMIDE HCL
 LEINER
 2MG
 N73254 001
 JUL 30, 1993
 NOVOPHARM NC
 2MG
 N73254 001
 JUL 30, 1993
 PERRIGO
 2MG
 N75232 001
 JAN 06, 2000

NAPROXEN SODIUM

TABLET; ORAL
 NAPROXEN SODIUM
 LEINER
 EQ 200MG BASE
 N74635 001
 JAN 13, 1997
 NOVOPHARM NC
 EQ 280MG BASE
 N74635 001
 JAN 13, 1997

PERMETHRIN

LOTION; TOPICAL
 PERMETHRIN
 ALPHARMA
 1%
 N75014 001
 MAR 28, 2000

PIPERONYL BUTOXIDE, PYRETHRINS
 AEROSOL; TOPICAL
 RID MOUSSE
 + PFIZER
 4%;EQ 0.33% BASE
 N21043 001
 MAR 07, 2000

RANITIDINE HYDROCHLORIDE

TABLET; ORAL
 RANITIDINE
 CHELSEA LABS
 EQ 75MG BASE
 N75212 001
 JAN 14, 2000
 CHEMINOR DRUGS
 EQ 75MG BASE
 N75294 001
 MAR 28, 2000
 GENPHARM
 EQ 75MG BASE
 N75497 001
 JAN 14, 2000
 LEINER
 EQ 75MG BASE
 N75094 001
 JUN 21, 1999
 RANBAXY
 EQ 75MG BASE
 N75132 001
 JAN 14, 2000
 TORPHARM
 EQ 75MG BASE
 N75254 001
 JAN 14, 2000
 ZENITH GOLDLINE
 EQ 75MG BASE
 N75167 001
 MAY 04, 2000
 RANITIDINE HCL
 EQ 75MG BASE
 N75296 001
 JAN 14, 2000
 NOVOPHARM
 EQ 75MG BASE
 N75094 001
 JUN 21, 1999

TABLET, EFFERVESCENT, ORAL

ZANTAC 75
 + GLAXO WELLCOME
 EQ 75MG BASE
 N20745 001
 FEB 26, 1998
 @ WARNER LAMBERT
 EQ 75MG BASE
 N20745 001
 FEB 26, 1998

TERBINAFINE HYDROCHLORIDE

SOLUTION; TOPICAL
 LAMISIL AT
 + NOVARTIS
 1%
 N21124 001
 MAR 17, 2000

**DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST**

3-1

CUMULATIVE SUPPLEMENT NUMBER 8 AUGUST '00

NO AUGUST 2000 APPROVALS

This data is provided to the Division of Data Management and Services from the Office of Orphan Products Development and it is not edited prior to publication.

Orphan Products Designations and Approvals List
January through August 2000

| Name: Generic Name TN=Trade Name | Indication Designated: | Sponsor & Address DD=Date Designated MA=Marketing Approval |
|---|--|--|
| 1- (11-dodecylamino-10-hydr oxyundecyl)-3,7-dimethylxa nthine hydrogen methanesulfonate TN= | Treatment of hormone refractory prostate carcinoma. | Cell Therapeutics, Inc. 201 Elliott Avenue West Suite 400 Seattle WA 98119 DD= 1/18/00 MA= |
| 3- (3,5-Dimethyl-1H-2ylmeth ylene)-1,3-dihydro-indol-2 -one TN= | Treatment of von Hippel-Lindau disease. | Sugen, Inc. 230 East Grand Ave. South San Francisco CA 94080 DD= 3/23/00 MA= |
| Abetimus TN= | Treatment of lupus nephritis. | La Jolla Pharmaceutical Co. 6455 Nancy Ridge Dr. San Diego CA 92121 DD= 7/28/00 MA= |
| Angiotensin 1-7 TN= | Treatment of neutropenia associated with autologous bone marrow transplantation. | Maret Pharmaceuticals 4041 MacArthur Blvd. Suite 375 Newport Beach CA 92660 DD= 2/16/00 MA= |
| Arsenic trioxide | Treatment of multiple myeloma. | Cell Therapeutics, Inc. 201 Elliott Ave. West, Suite Seattle WA 98119 DD= 4/28/00 MA= |

Orphan Products Designations and Approvals List
January through August 2000

| Name: Generic Name TN=Trade Name | Indication Designated: | Sponsor & Address DD=Date Designated MA=Marketing Approval |
|---|--|---|
| Arsenic trioxide TN=Atrivex | Treatment of myelodysplastic syndrome. | Cell Therapeutics, Inc. 201 Elliott Avenue West Suite 400 Seattle WA 98119 DD= 7/17/00 MA= |
| Bis(4-fluorophenyl) phenylacetamide TN= | Treatment of sickle cell disease. | ICAGEN Inc. Ion Channel Advances PO Box 14487 Durham NC 27709 DD= 3/2/00 MA= |
| Brimonidine TN=Alphagan | Treatment of anterior ischemic optic neuropathy. | Allergan, Inc. 2525 Dupont Dr. P.O. Box 19534 Irvine CA 92623-9534 DD= 2/7/00 MA= |
| Calfactant TN=Infasurf | Acute respiratory distress syndrome (ARDS) | ONY, Inc. Baird Research Park 1576 Sweet Home Road Amherst NY 14228 DD= 9/5/00 MA= |
| Carmustine TN= | Treatment of intracranial malignancies. | Direct Therapeutics, Inc. 1001 Bayhill Dr., Suite 100 San Bruno CA 94066 DD= 7/3/00 MA= |

Orphan Products Designations and Approvals List
January through August 2000

| Name: Generic Name TN=Trade Name | Indication Designated: | Sponsor & Address DD=Date Designated MA=Marketing Approval |
|--|--|---|
| Centruroides immune F(ab)2 TN=Alacramyn | Treatment of scorpion envenomations requiring medical attention. | Silanes Laboratories S.A. de Amores #1034 Col Del Valle C.P. 03100 Mexico D.F. DD= 6/12/00 MA= |
| Cetuximab TN= | Treatment of squamous cell cancer of the head and neck in patients who express epidermal growth factor receptor. | ImClone Systems Incorporated Branchburg Corporate Center 22 Chubb Way Somerville NJ 08876 DD= 7/3/00 MA= |
| Chimeric (human-murine) G250 IgG monoclonal antibody TN= | Treatment of renal cell carcinoma. | Wilex Biotechnology GmbH Grillparzerstrasse 10B 81675 Munich Germany DE DD= 7/24/00 MA= |
| Chimeric, humanized monoclonal antibody to staphylococcus TN= | Prophylaxis of Staphylococcus epidermidis sepsis in low birth weight (1500 grams or less) infants. | Biosynexus, Inc. 9610 Medical Center Drive Suite 100 Rockville MD 20850 DD= 8/3/00 MA= |

Orphan Products Designations and Approvals List
January through August 2000

| Name: Generic Name TN=Trade Name | Indication Designated: | Sponsor & Address DD=Date Designated MA=Marketing Approval |
|--|--|---|
| Cisplatin/epinephrine TN=IntraDose | Treatment of squamous cell carcinoma of the head and neck. | Matrix Pharmaceutical, Inc. 34700 Campus Drive Fremont CA 94555-3612 DD= 4/3/00 MA= |
| Deoxyribose, phosphorothioate TN= | Treatment of advanced malignant melanoma (Stages II,III, IV). | Genta, Inc. 99 Hayden Ave., Suite 200 Lexington MA 02421-7966 DD= 7/31/00 MA= |
| DNA-lipid complex (DMRIE/DOPE)/plasmid vector (VCL-1102, Vical) expressing human interleukin-2 TN=Leuvectin | Treatment of renal cell carcinoma. | Vical Incorporated 9373 Towne Center Dr. Suite 100 San Diego CA 92121-3088 DD= 4/28/00 MA= |
| Ethyl eicosapentaenoate TN= | Treatment of Huntington's disease. | Laxdale Ltd. Kings Park House, Laurelhill Polmaise Road, Stirling FK7 United Kingdom UK DD= 4/6/00 MA= |

Orphan Products Designations and Approvals List
January through August 2000

| Name: Generic Name TN=Trade Name | Indication Designated: | Sponsor & Address DD=Date Designated MA=Marketing Approval |
|--|---|--|
| Flucinolone TN= | Treatment uveitis involving the posterior segment of the eye. | Bausch & Lomb 8500 Hidden River Parkway Tampa FL 33637 DD= 7/31/00 MA= |
| Fluorouracil TN= | Treatment of glioblastoma multiforme. | Ethypharm SA 194 Bureaux de la Colline - 92213 Saint-Cloud Cedex France FR DD= 6/29/00 MA= |
| Halofuginone TN=Stenorol | Treatment of systemic sclerosis. | Collgard Biopharmaceuticals Textile House, 2 Koifman St. Tel-Aviv 68012 Israel IL DD= 2/7/00 MA= |
| Histamine TN=Maxamine | For use as an adjunct to cytokine therapy in the treatment of malignant melanoma. | Maxim Pharmaceuticals, Inc. 8899 University Center Lane Suite 400 San Diego CA 92122 DD= 2/1/00 MA= |

Orphan Products Designations and Approvals List
January through August 2000

| Name: Generic Name TN=Trade Name | Indication Designated: | Sponsor & Address DD=Date Designated MA=Marketing Approval |
|--|--|--|
| Hypericin TN= | Treatment of glioblastoma multiforme. | Nexell Therapeutics 2751 Centerville Rd., Suite Wilmington DE 19808 DD= 8/3/00 MA= |
| Hypericin TN= | Treatment of cutaneous T-cell lymphoma. | Nexell Therapeutics, Inc. 2751 Centerville Rd., Suite Wilmington DE 19808 DD= 2/7/00 MA= |
| IL-4 Pseudomonas Toxin Fusion Protein (IL-4 (38-37) -PE38KDEL) TN= | Treatment of astrocytic glioma. | Neurocrine Biosciences, Inc. 10555 Science Center Dr. San Diego CA 92121 DD= 4/6/00 MA= |
| Iodine I 131 bis(indium-diethylenetriam inepentaacetic acid)tyrosyllysine/hMN-14 x m734 F(ab') ₂ bispecific monoclonal antibody TN=Pentacea | Treatment of small-cell lung cancer. | IBC Pharmaceuticals, L.L.C. 300 American Rd. Morris Plains NJ 07950 DD= 2/22/00 MA= |

Orphan Products Designations and Approvals List
January through August 2000

| Name: | Indication Designated: | Sponsor & Address |
|--|--|---|
| Generic Name | | DD=Date Designated |
| TN=Trade Name | | MA=Marketing Approval |
| Levodopa and carbidopa TN=Duodopa | Treatment of late stage Parkinson's disease. | Nouvel Pharma, Inc. 11322 Acuff La. Lenexa KS 66215 DD= 1/18/00 MA= |
| Liposomal nystatin TN=Nyotran | Treatment of invasive fungal infections. | Aronex Pharmaceuticals, Inc. 8707 Technology Forest Place The Woodlands TX 77381-1191 DD= 6/13/00 MA= |
| Meropenem TN=Merrem IV | Management of acute pulmonary exacerbations, in cystic fibrosis patients, due to respiratory tract infection with susceptible organisms. | Zeneca Pharmaceuticals 1800 Concord Pike PO Box 15437 Wilmington DE 19850-5437 DD= 4/27/00 MA= |
| Natural human lymphoblastoid interferon-alpha TN= | Treatment of papillomavirus warts in the oral cavity of HIV positive patients. | Amarillo Biosciences. Inc. 800 West 9th Avenue Amarillo TX 79101 DD= 8/10/00 MA= |
| Natural human lymphoblastoid interferon-alpha TN= | Treatment of Behcet's disease. | Amarillo Biosciences, Inc. 800 West Ninth Avenue Amarillo TX 79101-3206 DD= 1/18/00 MA= |

Orphan Products Designations and Approvals List
January through August 2000

| Name: Generic Name TN=Trade Name | Indication Designated: | Sponsor & Address DD=Date Designated MA=Marketing Approval |
|---|--|---|
| Omega-3 (n-3) polyunsaturated fatty acids TN=Omacor | Treatment of IgA nephropathy. | Pronova Biocare, AS PO Box 420 1327 Lysaker Norway DD= 5/4/00 MA= |
| Phenylbutyrate TN= | Treatment of acute promyelocytic leukemia. | Elan Corporation 1300 Gould Dr. Gainesville GA 30504 DD= 1/19/00 MA= |
| Recombinant glycine ² -human glucagon-like peptide-2 TN= | Treatment of short bowel syndrome. | NPS Allelix Corp. 6850 Goreway Dr. Mississauga, Ontario L4V 1V7 Canada CA DD= 6/29/00 MA= |
| Recombinant human antithrombin III TN= | Treatment of antithrombin III dependent heparin resistance requiring anticoagulation. | AT III LLC c/o Genzyme Corporation 15 Pleasant St. Connector, Framingham MA 01701 DD= 4/6/00 MA= |
| Recombinant human insulin-like growth factor-I TN=PV802 | Treatment of short-bowel syndrome as a result of resection of the small bowel or as a result of congenital dysfunction of the intestines. | GroPep Pty Ltd. Gate 11, Victoria Dr. Adelaide SA 5000 Australia AU DD= 2/16/00 MA= |

Orphan Products Designations and Approvals List
January through August 2000

| Name: Generic Name TN=Trade Name | Indication Designated: | Sponsor & Address DD=Date Designated MA=Marketing Approval |
|--|---|--|
| Remacemide TN=Ecovia | Treatment of Huntington's disease. | AstraZeneca LP 725 Chesterbrook Blvd. Wayne PA 19087-5677 DD= 3/6/00 MA= |
| rSP-C lung surfactant TN=Ventecute | Treatment of adult respiratory distress syndrome. | Byk Gulden Pharmaceuticals Byk-Gulden StraBe 2 78467 Konstanz Germany DE DD= 4/3/00 MA= |
| Soluble complement receptor type 1 TN= | Prevention of post-cardiopulmonary bypass syndrome in children undergoing cardiopulmonary bypass. | Avant Immunotherapeutics, 119 Fourth Ave. Needham MA 02494-2725 DD= 3/6/00 MA= |
| Synthetic human secretin TN= | For use in conjunction with diagnostic procedures for pancreatic disorders to increase pancreatic fluid secretion. | ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring MD 20905-4176 DD= 3/7/00 MA= |

Orphan Products Designations and Approvals List
January through August 2000

| Name: Generic Name TN=Trade Name | Indication Designated: | Sponsor & Address DD=Date Designated MA=Marketing Approval |
|--|--|--|
| Synthetic porcine secretin TN= | For use in conjunction with diagnostic procedures for pancreatic disorders to increase pancreatic fluid secretion. | ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring MD 20905-4176 DD= 3/7/00 MA= |
| Technetium Tc 99m pterotetramide TN= | For the identification of ovarian carcinomas. | Endocyte, Inc. 1205 Kent Ave. Lafayette IN 47906 DD= 2/16/00 MA= |
| Tetraiodothyroacetic acid TN= | Suppression of thyroid stimulating hormone in patients with well-differentiated cancer of the thyroid gland. | Danforth, Jr., MD, Elliot University of Vermont 84 Beartown Rd. Underhill VT 05489 DD= 5/1/00 MA= |
| Thymalfasin TN=Zadaxin | Treatment of hepatocellular carcinoma. | SciClone Pharmaceuticals, 901 Mariner's Blvd., Suite San Mateo CA 94404 DD= 3/6/00 MA= |
| Trimetrexate TN=Neutrexin | Treatment of metastatic osteogenic sarcoma. | Medimmune Oncology, Inc. One Tower Bridge 100 Front St., Suite 400 West Conshohocken PA 19428 DD= 8/10/00 MA= |

Orphan Products Designations and Approvals List
January through August 2000

| Name: Generic Name TN=Trade Name | Indication Designated: | Sponsor & Address DD=Date Designated MA=Marketing Approval |
|--|---|--|
| Vapreotide TN=Octastatin | Treatment of gastrointestinal and pancreatic fistulas. | Debiopharm S.A. 17 rue des Terreaux CH-1000 Lausanne 9 Switzerland CH DD= 1/10/00 MA= |
| Vapreotide TN=Octastatin | Prevention of early postoperative complications following pancreatic resection. | Debiopharm S.A. 17 rue des Terreaux CH-1000 Lausanne 9 Switzerland CH DD= 3/6/00 MA= |
| Vapreotide TN=Octastatin | Treatment of esophageal variceal hemorrhage patients with portal hypertension. | Debiopharm S.A. 17 rue des Terreaux CH-1000 Lausanne 9 Switzerland CH DD= 1/10/00 MA= |
| vigabatrin TN=Sabril | Treatment of infantile spasms. | Aventis Pharmaceuticals Inc. P.O. Box 9627 Kansas City MO 64137 DD= 6/12/00 MA= |
| Zoledronate TN=Zometa, Zabel | Treatment of tumor induced hypercalcemia. | Novartis Pharmaceuticals 59 Route 10 East Hanover NJ 07936-1080 DD= 8/18/00 MA= |

**DRUG PRODUCTS WHICH MUST DEMONSTRATE *IN VIVO* BIOAVAILABILITY ONLY
IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION**

NO AUGUST 2000 ADDITIONS

PRESCRIPTION AND OTC DRUG PRODUCT
 PATENT AND EXCLUSIVITY DATA
 *PED and PED represent Pediatric Exclusivity

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PEX EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|------------------|--|---------------|-------------------------|----------|-------------|----------------|
| 075077 001 | ACETAMINOPHEN; ACETAMINOPHEN | 4717720 | MAY 31, 2010 | | PC | NOV 12, 2000 |
| 020338 001 | ADAPALENE; DIFFERIN | 4717720 | MAY 31, 2010 | | | |
| 020380 001 | ADAPALENE; DIFFERIN | 4717720 | MAY 31, 2010 | | NCE | MAY 31, 2001 |
| 020748 001 | ADAPALENE; DIFFERIN | RE34440 | MAY 31, 2010 | | U-275 | MAY 26, 2003 |
| 020760 001 | ALATROFLOXACIN MESYLATE; TROVAN PRESERVATIVE | 6080756 | JUL 05, 2016 | | | |
| 020560 001 | ALATROFLOXACIN MESYLATE; TROVAN PRESERVATIVE | 608207 | JUN 06, 2015 | | U-303 M-3 | NOV 24, 2002 |
| 020560 002 | ALENDRONATE SODIUM; FOSAMAX | 6090410 | DEC 02, 2012 | | | |
| 020560 003 | ALENDRONATE SODIUM; FOSAMAX | 6090410 | DEC 02, 2012 | | U-303 M-3 | NOV 24, 2002 |
| 021107 001 | ALOSETRON HYDROCHLORIDE; LOTRONEX | 6090410 | DEC 02, 2012 | | U-303 M-3 | NOV 24, 2002 |
| >ADD> | | 4508726 | SEP 16, 2002 | | NCE | FEB 09, 2005 |
| >ADD> | | 4508726 | SEP 16, 2002 | | U-46 | |
| >ADD> | | 4508726 | SEP 16, 2002 | | U-46 | |
| >ADD> | | 4508726 | SEP 16, 2002 | | U-46 | |
| 020221 001 | AMIFOSTINE; ETHYOL | 5723490 | MAR 03, 2013 | | I-283 | JUN 24, 2002 |
| 020221 002 | AMIFOSTINE; ETHYOL | 5723490 | MAR 03, 2013 | | I-283 | JUN 24, 2002 |
| 021007 001 | AMPRENAVIR; AGENERASE | RE36617 | DEC 27, 2009 | | | |
| 021007 002 | AMPRENAVIR; AGENERASE | 5723490 | MAR 03, 2013 | | U-257 | |
| 021039 001 | AMPRENAVIR; AGENERASE | 5646180 | JUL 08, 2014 | | U-257 | |
| 020541 001 | ANASTROZOLE; ARIMIDEX | 5585397 | DEC 17, 2013 | | | |
| 020883 001 | ARGATROBAN; ACOVA | 5723490 | MAR 03, 2015 | | U-257 | |
| 020971 001 | ARTICAINE HYDROCHLORIDE; SEPTOCAINE | 5646180 | JUL 08, 2014 | | U-257 | |
| 021127 001 | AZELASTINE HYDROCHLORIDE; OPTIVAR | 5585397 | DEC 17, 2013 | | | |
| 020610 001 | BALSALAZIDE DISODIUM; COLAZAL | 5723490 | MAR 03, 2015 | | U-257 | |
| 021055 001 | BEXAROTENE; TARGRETIN | 5646180 | JUL 08, 2014 | | | |
| 021056 001 | BEXAROTENE; TARGRETIN | 5585397 | DEC 17, 2013 | | | |
| 019982 001 | BISOPROLOL FUMARATE; ZEBETA | 5723490 | MAR 03, 2015 | | U-257 | |
| 019982 002 | BISOPROLOL FUMARATE; ZEBETA | 5646180 | JUL 08, 2014 | | U-257 | |
| 020186 001 | BISOPROLOL FUMARATE; ZIAC | RE36617 | DEC 27, 2009 | | | |
| | | 5164194 | NOV 01, 2010 | | NCE | JUN 30, 2005 |
| | | 5164194* | MAY 01, 2011 | | NC | APR 03, 2003 |
| | | 4412992 | JUL 08, 2001 | | NCE | NOV 01, 2001 |
| | | 4258062 | MAR 24, 2000 | | NDF | MAY 22, 2003 |
| | | 4258062*PED | SEP 24, 2000 | | PED | MAY 01, 2002 |
| | | 4258062 | MAR 24, 2000 | | PED | NOV 22, 2003 |
| | | 4258062*PED | SEP 24, 2000 | | NCE | JUL 18, 2005 |
| | | 4258062 | MAR 24, 2000 | | ODE | DEC 29, 2006 |
| | | 4258062*PED | SEP 24, 2000 | | NCE | DEC 29, 2004 |
| | | 4258062 | MAR 24, 2000 | | | |
| | | 4258062*PED | SEP 24, 2000 | | U-63 | |
| | | 4258062 | MAR 24, 2000 | | U-63 | |
| | | 4258062*PED | SEP 24, 2000 | | U-63 | |
| | | 4258062 | MAR 24, 2000 | | U-63 | |
| | | 4258062*PED | SEP 24, 2000 | | U-63 | |

PRESCRIPTION AND OTC DRUG PRODUCT
 PATENT AND EXCLUSIVITY DATA
 *PED and PED represent Pediatric Exclusivity

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | EXCL CODE | EXCLUS EXPIRES |
|------------------|-------------------------------------|---------------|-------------------------|-----------|--------------------|
| 018998 005 | ENALAPRIL MALEATE; VASOTEC | 4374829 | FEB 22, 2000 | | |
| 019309 001 | ENALAPRILAT; VASOTEC | 4374829*PED | AUG 22, 2000 | | |
| 020444 001 | EPOPROSTENOL SODIUM; FLOLAN | 4374829 | FEB 22, 2000 | | |
| 020444 002 | EPOPROSTENOL SODIUM; FLOLAN | 4374829*PED | AUG 22, 2000 | | |
| 020907 001 | ESTRADIOL; ACTIVELLE | 5122383 | MAY 17, 2011 | | ODE APR 14, 2007 |
| 020655 001 | ESTRADIOL; ALORA | 5227169 | MAY 17, 2011 | | I-296 APR 14, 2003 |
| | | 5212199 | MAY 17, 2011 | | I-296 APR 14, 2003 |
| | | 5164190 | DEC 11, 2010 | | I-295 APR 11, 2003 |
| 020655 002 | ESTRADIOL; ALORA | 5122383 | MAY 17, 2011 | | |
| | | 5227169 | MAY 17, 2011 | | |
| | | 5212199 | MAY 17, 2011 | | |
| | | 5164190 | DEC 11, 2010 | | |
| 020655 003 | ESTRADIOL; ALORA | 5122383 | MAY 17, 2011 | | |
| | | 5227169 | MAY 17, 2011 | | |
| | | 5212199 | MAY 17, 2011 | | |
| | | 5164190 | DEC 11, 2010 | | |
| 021040 001 | ESTRADIOL; ORTHO-PREFEST | 5108995 | APR 28, 2009 | U-311 | |
| | | 5382573 | JAN 17, 2012 | | |
| 020323 001 | ESTRADIOL; VIVELLE | 4994278 | MAR 04, 2008 | | I-254 AUG 16, 2003 |
| 020323 002 | ESTRADIOL; VIVELLE | 5300291 | APR 05, 2011 | | I-254 AUG 16, 2003 |
| 020323 003 | ESTRADIOL; VIVELLE | 4814168 | APR 04, 2008 | | I-254 AUG 16, 2003 |
| 020323 004 | ESTRADIOL; VIVELLE | 4994278 | MAR 04, 2008 | | NS AUG 16, 2003 |
| 020323 005 | ESTRADIOL; VIVELLE | 4814168 | APR 04, 2008 | | I-254 AUG 16, 2003 |
| | | 4994278 | MAR 04, 2008 | | |
| 075696 001 | ETODOLAC; ETODOLAC | 4966768*PED | APR 30, 2008 | | PC FEB 04, 2001 |
| 020584 001 | ETODOLAC; LODINE XL | 4966768 | OCT 30, 2007 | | |
| 020584 002 | ETODOLAC; LODINE XL | 4966768*PED | APR 30, 2008 | | |
| 020584 003 | ETODOLAC; LODINE XL | 4966768 | OCT 30, 2007 | | |
| 019304 002 | FENOFIBRATE; TRICOR (MICRONIZED) | 4966768*PED | APR 30, 2007 | | |
| 019304 003 | FENOFIBRATE; TRICOR (MICRONIZED) | 4966768 | OCT 30, 2007 | | |
| 019304 004 | FENOFIBRATE; TRICOR (MICRONIZED) | 4966768 | OCT 30, 2007 | | |
| 020625 001 | FEXOFENADINE HYDROCHLORIDE; ALLEGRA | 4966768*PED | APR 30, 2008 | | |
| | | 4966768 | OCT 30, 2007 | | |
| 020872 001 | FEXOFENADINE HYDROCHLORIDE; ALLEGRA | 6113942 | FEB 28, 2015 | | I-298 APR 24, 2003 |
| | | 6037353 | MAR 14, 2017 | U-138 | I-298 APR 24, 2003 |
| | | 6113942 | FEB 28, 2015 | | I-298 APR 24, 2003 |
| | | 5578610 | NOV 26, 2013 | | |
| | | 5932247 | FEB 28, 2015 | | |
| | | 5855912 | FEB 28, 2015 | | |
| | | 4254129 | FEB 17, 2001 | | |
| | | 6037353 | MAR 14, 2017 | | |
| | | | | U-139 | |
| | | | | U-138 | |
| | | | | NDF | FEB 25, 2003 |

PRESCRIPTION AND OTC DRUG PRODUCT
 PATENT AND EXCLUSIVITY DATA
 *PED and PED represent Pediatric Exclusivity

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXPIRES | EXCL CODE | EXCLUS CODE | EXCLUS EXPIRES |
|------------------|---|---------------|--------------------|-----------|-------------|----------------|
| >ADD> 020872 002 | FEXOFENADINE HYDROCHLORIDE; ALLEGRA | 6113942 | FEB 28, 2015 | U-139 | NDF | FEB 25, 2003 |
| | | 5578610 | NOV 26, 2013 | | | |
| | | 5932247 | FEB 28, 2015 | | | |
| | | 5855912 | FEB 28, 2015 | | | |
| | | 4254129 | FEB 17, 2001 | U-139 | | |
| | | 6037353 | MAR 14, 2017 | U-138 | | |
| >ADD> 020872 004 | FEXOFENADINE HYDROCHLORIDE; ALLEGRA | 6113942 | FEB 28, 2015 | U-139 | NDF | FEB 25, 2003 |
| | | 5578610 | NOV 26, 2013 | | | |
| | | 5932247 | FEB 28, 2015 | | | |
| | | 5855912 | FEB 28, 2015 | | | |
| | | 4254129 | FEB 17, 2001 | U-139 | | |
| | | 6037353 | MAR 14, 2017 | U-138 | | |
| >ADD> 020786 001 | FEXOFENADINE HYDROCHLORIDE; ALLEGRA-D | 6113942 | FEB 28, 2015 | U-138 | | |
| | | 6037353 | MAR 14, 2017 | U-138 | | |
| | | 6039974 | JUL 31, 2018 | | | |
| | | 4416682 | JUN 02, 2001 | | | |
| | | 4404216 | JAN 29, 2004 | | | |
| 019949 004 | FLUCONAZOLE; DIFLUCAN | 4971998 | NOV 20, 2007 | U-338 NP | | JUL 06, 2003 |
| >ADD> 018936 007 | FLUOXETINE HYDROCHLORIDE; SARAFEM | 5114976 | MAY 19, 2009 | U-341 | | |
| >ADD> | | 5744501 | MAY 19, 2009 | U-342 | | |
| >ADD> | | 4971998 | NOV 20, 2007 | U-338 NP | | JUL 06, 2003 |
| >ADD> | | 5114976 | MAY 19, 2009 | U-341 | | |
| >ADD> | | 5744501 | MAY 19, 2009 | U-342 | | |
| 021077 001 | FLUTICASON PROPIONATE; ADVAIR DISKUS 100/50 | | | NC | | AUG 24, 2003 |
| >ADD> 021077 002 | FLUTICASON PROPIONATE; ADVAIR DISKUS 250/50 | | | NC | | AUG 24, 2003 |
| >ADD> 021077 003 | FLUTICASON PROPIONATE; ADVAIR DISKUS 500/50 | | | NC | | AUG 24, 2003 |
| 020378 001 | FOLLITROPIN ALFA/BETA; GONAL-F | | | ODE | | MAY 24, 2007 |
| >ADD> | | | | I-306 | | MAY 24, 2003 |
| >ADD> | | | | ODE | | MAY 24, 2007 |
| 020378 002 | FOLLITROPIN ALFA/BETA; GONAL-F | | | I-306 | | MAY 24, 2007 |
| 020235 001 | GABAPENTIN; NEURONTIN | 4087544 | JAN 16, 2000 | U-86 | | MAR 29, 2002 |
| | | 5084479 | JAN 02, 2010 | U-125 | | SEP 29, 2001 |
| | | 4894476*PED | NOV 02, 2008 | | | |
| | | 4087544*PED | NOV 02, 2008 | | | |
| | | 5084479*PED | JUL 16, 2000 | U-86 | | |
| | | 4894476 | JUL 02, 2010 | U-125 | | |
| | | 6054482 | MAY 02, 2008 | | | |
| | | 6054482 | MAY 02, 2017 | | | |
| | | 6054482*PED | OCT 25, 2017 | | | |
| | | 4894476 | MAY 02, 2008 | | | |
| | | 5084479 | MAY 02, 2008 | | | |
| | | 5084479 | JAN 02, 2010 | U-125 | | MAR 29, 2002 |
| | | 4087544 | JAN 16, 2000 | U-86 | | SEP 29, 2001 |
| | | 5084479*PED | JUL 02, 2010 | U-125 | | |
| | | 4894476*PED | NOV 02, 2008 | | | |
| | | 4087544*PED | JUL 16, 2000 | U-86 | | |
| | | 6054482 | APR 25, 2017 | | | |
| 020235 002 | GABAPENTIN; NEURONTIN | 6054482*PED | OCT 25, 2017 | | | |

PRESCRIPTION AND OTC DRUG PRODUCT
 PATENT AND EXCLUSIVITY DATA
 *PED and PED represent Pediatric Exclusivity

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|------------------|--------------------------------------|---------------|-------------------------|----------|-------------|----------------|
| >ADD> | | 5047407 | NOV 17, 2009 | | NCE | NOV 17, 2000 |
| >ADD> | LAMIVUDINE; EPIVIR | 6004968 | MAR 20, 2018 | | PED | MAY 17, 2001 |
| >ADD> | | 6004968*PED | SEP 20, 2018 | | | |
| >ADD> | | 5047407*PED | MAY 17, 2010 | | | |
| >ADD> | LAMIVUDINE; EPIVIR-HBV | 5047407 | FEB 08, 2009 | | I-257 | DEC 08, 2001 |
| >ADD> | | 5532246 | JUL 02, 2013 | | PED | JUN 08, 2002 |
| >ADD> | | 5905082 | MAY 18, 2016 | | | |
| >ADD> | | 5047407*PED | AUG 08, 2009 | | | |
| >ADD> | | 5532246*PED | JAN 02, 2014 | | | |
| >ADD> | | 5905082*PED | NOV 18, 2016 | | | |
| >ADD> | LAMIVUDINE; EPIVIR-HBV | 5047407 | FEB 08, 2009 | | NCE | NOV 17, 2000 |
| >ADD> | | 5532246 | JUL 02, 2013 | | I-257 | DEC 08, 2001 |
| >ADD> | | 6004968 | MAR 20, 2018 | | PED | MAY 17, 2001 |
| >ADD> | | 5047407*PED | AUG 08, 2009 | | PED | JUN 08, 2002 |
| >ADD> | | 5532246*PED | JAN 02, 2014 | | | |
| >ADD> | | 6004968*PED | SEP 20, 2018 | | | |
| >ADD> | LEUPROLIDE ACETATE; VIADUR | 5728396 | JAN 30, 2017 | | U-250 | |
| >ADD> | | 5932547 | JUN 13, 2017 | | | |
| >ADD> | | 5985305 | JAN 30, 2017 | | | |
| >ADD> | LEVALBUTEROL HYDROCHLORIDE; XOPENEX | 5362755 | NOV 08, 2011 | | U-332 | |
| >ADD> | | 5547994 | AUG 20, 2013 | | U-332 | |
| >ADD> | | 5760090 | JAN 05, 2010 | | U-332 | |
| >ADD> | | 5844002 | JAN 05, 2010 | | U-332 | |
| >ADD> | LEVALBUTEROL HYDROCHLORIDE; XOPENEX | 5362755 | NOV 08, 2011 | | U-332 | |
| >ADD> | | 5547994 | AUG 20, 2013 | | U-332 | |
| >ADD> | | 5760090 | JAN 05, 2010 | | U-332 | |
| >ADD> | | 5844002 | JAN 05, 2010 | | U-332 | |
| >ADD> | LEVOBETAXOLOL HYDROCHLORIDE; BETAXON | | | | NP | FEB 23, 2003 |
| >ADD> | LEVOFLOXACIN; LEVAQUIN | | | | I-305 | FEB 02, 2003 |
| >ADD> | LEVOFLOXACIN; LEVAQUIN | | | | I-305 | FEB 02, 2003 |
| >ADD> | LEVOFLOXACIN; LEVAQUIN | | | | I-305 | FEB 02, 2003 |
| >ADD> | LEVOFLOXACIN; LEVAQUIN IN DEXTROSE | | | | I-305 | FEB 02, 2003 |
| >ADD> | LEVOFLOXACIN; LEVAQUIN IN DEXTROSE | | | | I-305 | FEB 02, 2003 |
| >ADD> | LEVOFLOXACIN; LEVAQUIN IN DEXTROSE | | | | NDP | AUG 18, 2003 |
| >ADD> | | 4382892 | SEP 02, 2003 | | | |
| >ADD> | | 5503407 | OCT 01, 2008 | | | |
| >ADD> | | 4551456 | NOV 14, 2003 | | | |
| >ADD> | LIDOCAINE; LIDODERM | | | | NP | MAR 19, 2002 |
| >ADD> | LINEZOLID; ZYVOX | 5688792 | NOV 18, 2014 | | U-319 | APR 18, 2005 |
| >ADD> | LINEZOLID; ZYVOX | 5688792 | NOV 18, 2014 | | U-319 | APR 18, 2005 |
| >ADD> | LINEZOLID; ZYVOX | 5688792 | NOV 18, 2014 | | U-319 | APR 18, 2005 |
| >ADD> | LINEZOLID; ZYVOX | 5688792 | NOV 18, 2014 | | U-319 | APR 18, 2005 |
| >ADD> | LISINAPRIL; PRINIVIL | 4374829 | DEC 29, 2001 | | | |
| >ADD> | LISINAPRIL; PRINIVIL | 4374829 | DEC 29, 2001 | | | |
| >ADD> | LISINAPRIL; PRINIVIL | 4374829 | DEC 29, 2001 | | | |

PRESCRIPTION AND OTC DRUG PRODUCT
 PATENT AND EXCLUSIVITY DATA
 *PED and PED represent Pediatric Exclusivity

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXPIRES | EXCL CODE | EXCLUS CODE | EXCLUS EXPIRES |
|------------------|-------------------------------|---------------|--------------------|-----------|-------------|----------------|
| 019558 004 | LISINAPRIL; PRINIVIL | 4374829 | DEC 29, 2001 | | I-288 | FEB 07, 2003 |
| 019558 006 | LISINAPRIL; PRINIVIL | 4374829 | DEC 29, 2001 | | I-288 | FEB 07, 2003 |
| 019777 001 | LISINAPRIL; ZESTRIL | | | | I-288 | FEB 07, 2003 |
| 019777 002 | LISINAPRIL; ZESTRIL | | | | I-288 | FEB 07, 2003 |
| 019777 003 | LISINAPRIL; ZESTRIL | | | | I-288 | FEB 07, 2003 |
| 019777 004 | LISINAPRIL; ZESTRIL | | | | I-288 | FEB 07, 2003 |
| 019777 005 | LISINAPRIL; ZESTRIL | | | | I-288 | FEB 07, 2003 |
| 019777 006 | LISINAPRIL; ZESTRIL | | | | I-288 | FEB 07, 2003 |
| 019658 001 | LORATADINE; CLARITIN | | | | I-288 | FEB 07, 2003 |
| 020641 001 | LORATADINE; CLARITIN | | | | | |
| | | 4282233 | JUN 19, 2002 | U-77 | | |
| | | 4659716 | APR 21, 2004 | U-142 | | |
| | | 4863931 | SEP 15, 2008 | | | |
| | | 4282233*PED | DEC 19, 2002 | U-77 | | |
| | | 4659716*PED | OCT 21, 2004 | U-142 | | |
| | | 4863931*PED | MAR 15, 2009 | | | |
| | | 4282233 | APR 21, 2004 | U-142 | | |
| | | 4659716 | JUN 19, 2002 | U-77 | | |
| | | 4863931 | SEP 15, 2008 | | | |
| | | 4659716*PED | OCT 21, 2004 | U-142 | | |
| | | 4863931*PED | MAR 15, 2009 | | | |
| 020704 001 | LORATADINE; CLARITIN REDITABS | | | | | |
| | | 4282233 | APR 21, 2004 | U-77 | | |
| | | 4659716 | APR 21, 2004 | U-142 | | |
| | | 4371516 | JUN 19, 2002 | U-77 | | |
| | | 4863931 | FEB 01, 2000 | | | |
| | | 4659716*PED | SEP 15, 2008 | | | |
| | | 4863931*PED | OCT 21, 2004 | U-142 | | |
| | | 4282233*PED | DEC 19, 2002 | U-77 | | |
| | | 4371516*PED | AUG 01, 2000 | U-142 | | |
| | | 4863931*PED | MAR 15, 2009 | | | |
| 019670 001 | LORATADINE; CLARITIN-D | | | | | |
| | | 4282233 | JUN 19, 2002 | U-77 | | |
| | | 4659716 | APR 21, 2004 | U-142 | | |
| | | 4863931 | SEP 15, 2008 | | | |
| | | 4282233*PED | DEC 19, 2002 | U-77 | | |
| | | 4659716*PED | OCT 21, 2004 | U-142 | | |
| | | 4863931*PED | MAR 15, 2009 | | | |
| | | 4282233 | JUN 19, 2002 | U-77 | | |
| | | 5314697 | APR 23, 2013 | | | |
| | | 4282233*PED | DEC 19, 2002 | U-77 | | |
| | | 4659716 | APR 21, 2004 | U-142 | | |
| | | 4863931*PED | MAR 15, 2009 | | | |
| | | 4863931 | SEP 15, 2008 | | | |
| | | 4659716*PED | OCT 21, 2004 | U-142 | | |
| | | 4966335 | MAR 09, 2012 | | | |
| | | 4966335 | MAR 09, 2012 | | | |

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PRESCRIPTION AND OTC DRUG PRODUCT
 PATENT AND EXCLUSIVITY DATA
 *PED and PED represent Pediatric Exclusivity

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL USE EXPIRES | EXCLUS CODE | EXCLUS EXPIRES |
|------------------|---|---------------|-----------------------------|-------------|----------------|
| 020938 001 | MELOXICAM; MOBIC | 4980173 | JAN 29, 2002 | U-78 | APR 13, 2005 |
| 020049 001 | MESALAMINE; PENTASA | 5696172 | OCT 06, 2013 | | |
| 019884 001 | MESNA; MESNEX | | | | |
| 020357 001 | METFORMIN HYDROCHLORIDE; GLUCOPHAGE | | | | |
| >ADD> | | | | | |
| >ADD> | | | | | |
| 020357 002 | METFORMIN HYDROCHLORIDE; GLUCOPHAGE | | | | |
| >ADD> | | | | | |
| 020357 003 | METFORMIN HYDROCHLORIDE; GLUCOPHAGE | | | | |
| >ADD> | | | | | |
| 020357 004 | METFORMIN HYDROCHLORIDE; GLUCOPHAGE | | | | |
| >ADD> | | | | | |
| >ADD> | | | | | |
| >ADD> | | | | | |
| 020357 005 | METFORMIN HYDROCHLORIDE; GLUCOPHAGE | | | | |
| >ADD> | | | | | |
| >ADD> | | | | | |
| 021121 001 | METHYLPHENIDATE HYDROCHLORIDE; CONCERTA | | | | |
| 021121 002 | METHYLPHENIDATE HYDROCHLORIDE; CONCERTA | | | | |
| 019815 001 | MIDODRINE HYDROCHLORIDE; PROAMATINE | | | | |
| 019815 002 | MIDODRINE HYDROCHLORIDE; PROAMATINE | | | | |
| 020830 002 | MONTELUKAST SODIUM; SINGULAIR | 5565473 | NOV 30, 2010 | U-228 | |
| 019516 001 | MORPHINE SULFATE; MS CONTIN | 4366310 | DEC 10, 2000 | | |
| 019516 002 | MORPHINE SULFATE; MS CONTIN | 4366310 | DEC 10, 2000 | | |
| 019516 003 | MORPHINE SULFATE; MS CONTIN | 4366310 | DEC 10, 2000 | | |
| 019516 004 | MORPHINE SULFATE; MS CONTIN | 4366310 | DEC 10, 2000 | | |
| 019516 005 | MORPHINE SULFATE; MS CONTIN | 4366310 | DEC 10, 2000 | | |
| 020152 001 | NEFAZODONE HYDROCHLORIDE; SERZONE | 5256664 | APR 28, 2012 | | |
| 020152 002 | NEFAZODONE HYDROCHLORIDE; SERZONE | 5256664 | APR 28, 2012 | | |
| 020152 003 | NEFAZODONE HYDROCHLORIDE; SERZONE | 5256664 | APR 28, 2012 | | |
| 020152 004 | NEFAZODONE HYDROCHLORIDE; SERZONE | 5256664 | APR 28, 2012 | | |
| 020152 005 | NEFAZODONE HYDROCHLORIDE; SERZONE | 5256664 | APR 28, 2012 | | |
| 020152 006 | NEFAZODONE HYDROCHLORIDE; SERZONE | 5256664 | APR 28, 2012 | | |
| 020381 001 | NIACIN; NIASPAN | 6080428 | MAY 27, 2017 | U-331 | |
| 020381 002 | NIACIN; NIASPAN | 6080428 | MAY 27, 2017 | U-331 | |
| 020381 003 | NIACIN; NIASPAN | 6080428 | MAY 27, 2017 | U-331 | |

PRESCRIPTION AND OTC DRUG PRODUCT
 PATENT AND EXCLUSIVITY DATA
 *PED and PED represent Pediatric Exclusivity

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|------------------|------------------------------|---------------|-------------------------|----------|-------------|----------------|
| 020381 004 | NIACIN; NIASPAN | 6080428 | MAY 27, 2017 | U-331 | | |
| 020381 005 | NIACIN; NIASPAN TITRATION ST | 6080428 | MAY 27, 2017 | U-331 | | |
| 020536 001 | NICOTINE; NICOTROL | 5501236 | JUN 08, 2010 | | | |
| | | 6098632 | JUN 08, 2010 | | | |
| | | 6098632 | JUN 08, 2010 | | | |
| 020714 001 | NICOTINE; NICOTROL | | | | | |
| 021134 001 | NITROGLYCERIN; NITROSTAT | | | | NDF | MAY 01, 2003 |
| 021134 002 | NITROGLYCERIN; NITROSTAT | | | | NDF | MAY 01, 2003 |
| 021134 003 | NITROGLYCERIN; NITROSTAT | | | | NDF | MAY 01, 2003 |
| 019921 001 | OFLOXACIN; OCUFLOX | 4382892 | SEP 02, 2003 | | | |
| | | 4551456 | NOV 14, 2003 | U-80 | | |
| 020592 001 | OLANZAPINE; ZYPREXA | | | | | |
| 020592 002 | OLANZAPINE; ZYPREXA | | | | I-297 | MAR 17, 2003 |
| 020592 003 | OLANZAPINE; ZYPREXA | | | | I-297 | MAR 17, 2003 |
| 020592 004 | OLANZAPINE; ZYPREXA | | | | I-297 | MAR 17, 2003 |
| 020592 005 | OLANZAPINE; ZYPREXA | | | | I-297 | MAR 17, 2003 |
| 020592 006 | OLANZAPINE; ZYPREXA | | | | I-297 | MAR 17, 2003 |
| 021086 001 | OLANZAPINE; ZYPREXA ZYDIS | | | | NCE | SEP 30, 2001 |
| | | 5457895 | SEP 30, 2013 | | | |
| | | 5229382 | APR 23, 2011 | U-324 | | |
| | | 5605897 | FEB 25, 2014 | U-325 | | |
| | | 5627178 | APR 23, 2011 | U-326 | | |
| | | 5736541 | MAR 24, 2015 | U-328 | | |
| | | 5817655 | APR 23, 2011 | U-327 | | |
| | | 5817656 | APR 23, 2011 | U-326 | | |
| | | 5457895 | SEP 30, 2013 | | NCE | SEP 30, 2001 |
| | | 5229382 | APR 23, 2011 | U-324 | | |
| | | 5605897 | FEB 25, 2014 | U-325 | | |
| | | 5627178 | APR 23, 2011 | U-326 | | |
| | | 5736541 | MAR 24, 2015 | U-328 | | |
| | | 5817655 | APR 23, 2011 | U-327 | | |
| | | 5817656 | APR 23, 2011 | U-326 | | |
| 021086 002 | OLANZAPINE; ZYPREXA ZYDIS | | | | | |
| | | 5457895 | SEP 30, 2013 | | NCE | SEP 30, 2001 |
| | | 5736541 | MAR 24, 2015 | U-328 | | |
| | | 5817655 | APR 23, 2011 | U-327 | | |
| | | 5817656 | APR 23, 2011 | U-326 | | |
| | | 5229382 | APR 23, 2011 | U-324 | | |
| | | 5605897 | FEB 25, 2014 | U-325 | | |
| | | 5627178 | APR 23, 2011 | U-326 | | |
| | | 5457895 | SEP 30, 2013 | | NCE | SEP 30, 2001 |
| 021086 003 | OLANZAPINE; ZYPREXA ZYDIS | | | | | |
| | | 5457895 | SEP 30, 2013 | | NCE | SEP 30, 2001 |
| | | 5736541 | MAR 24, 2015 | U-328 | | |
| | | 5817655 | APR 23, 2011 | U-327 | | |
| | | 5817656 | APR 23, 2011 | U-326 | | |
| | | 5229382 | APR 23, 2011 | U-324 | | |
| | | 5605897 | FEB 25, 2014 | U-325 | | |
| | | 5627178 | APR 23, 2011 | U-326 | | |
| | | 5457895 | SEP 30, 2013 | | NCE | SEP 30, 2001 |
| 021086 004 | OLANZAPINE; ZYPREXA ZYDIS | | | | | |
| | | 5457895 | SEP 30, 2013 | | NCE | SEP 30, 2001 |
| | | 5229382 | APR 23, 2011 | U-324 | | |
| | | 5605897 | FEB 25, 2014 | U-325 | | |
| | | 5627178 | APR 23, 2011 | U-326 | | |
| | | 5736541 | MAR 24, 2015 | U-328 | | |
| | | 5817655 | APR 23, 2011 | U-327 | | |
| | | 5817656 | APR 23, 2011 | U-326 | | |

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PRESCRIPTION AND OTC DRUG PRODUCT
 PATENT AND EXCLUSIVITY DATA
 *PED and PED represent Pediatric Exclusivity

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|------------------|------------------------------------|---------------|-------------------------|----------|-------------|----------------|
| 020688 001 | OLOPATADINE HYDROCHLORIDE; PATANOL | 4559330 | JUL 31, 2004 | U-58 | I-301 | MAR 20, 2003 |
| 019715 001 | OLSALAZINE SODIUM; DIPENTUM | 5344658 | SEP 06, 2011 | | | |
| 020103 001 | ONDANSETRON HYDROCHLORIDE; ZOFRAN | 5344658 | SEP 06, 2011 | | I-269 | AUG 27, 2002 |
| 020103 002 | ONDANSETRON HYDROCHLORIDE; ZOFRAN | 5344658 | SEP 06, 2011 | | | |
| 020103 003 | ONDANSETRON HYDROCHLORIDE; ZOFRAN | 5578628 | JUN 24, 2006 | U-44 | | |
| | | 4753789 | JUN 24, 2006 | U-44 | | |
| | | 4695578 | JAN 25, 2005 | | | |
| 020605 001 | ONDANSETRON HYDROCHLORIDE; ZOFRAN | 4695578 | JAN 25, 2005 | | U-183 | |
| 020781 001 | ONDANSETRON; ZOFRAN ODT | 5955488 | NOV 14, 2015 | | | |
| | | 6063802 | NOV 14, 2015 | | | |
| | | 5578628 | JUN 24, 2006 | U-330 | | |
| | | 4695578 | JAN 25, 2005 | U-330 | | |
| | | 4753789 | JUN 24, 2006 | U-329 | | |
| | | 5955488 | NOV 14, 2015 | | | |
| 020781 002 | ONDANSETRON; ZOFRAN ODT | 6063802 | NOV 14, 2015 | | | |
| | | 5578628 | JUN 24, 2006 | U-330 | | |
| | | 4695578 | JAN 25, 2005 | U-330 | | |
| | | 4753789 | JUN 24, 2006 | U-330 | | |
| | | 6004996 | JAN 06, 2018 | | | |
| 020766 001 | ORLISTAT; XENICAL | 6096331 | FEB 22, 2013 | | NCE | JAN 14, 2005 |
| 021014 001 | OXCARBAZEPINE; TRILEPTAL | 4758579 | JUL 19, 2005 | | NCE | JAN 14, 2005 |
| 021014 002 | OXCARBAZEPINE; TRILEPTAL | 5246925 | SEP 21, 2010 | | NCE | JAN 14, 2005 |
| 021014 003 | OXCARBAZEPINE; TRILEPTAL | 5587497 | DEC 24, 2013 | | D-57 | JUN 20, 2003 |
| 020262 001 | PACLITAXEL; TAXOL | 6063927 | APR 23, 2019 | | NCE | FEB 02, 2005 |
| 020987 001 | PANTOPRAZOLE SODIUM; PROTONIX | 6080759 | MAY 19, 2015 | | | |
| 020819 001 | PARICALCITOL; ZEMPLAR | 6080759 | MAY 19, 2015 | U-314 | | |
| 020031 001 | PAROXETINE HYDROCHLORIDE; PAXIL | 6063927 | APR 23, 2019 | | | |
| 020031 002 | PAROXETINE HYDROCHLORIDE; PAXIL | 6080759 | MAY 19, 2015 | | | |
| 020031 003 | PAROXETINE HYDROCHLORIDE; PAXIL | 6063927 | APR 23, 2019 | | | |
| 020031 004 | PAROXETINE HYDROCHLORIDE; PAXIL | 6080759 | MAY 19, 2015 | | | |
| 020031 005 | PAROXETINE HYDROCHLORIDE; PAXIL | 6063927 | APR 23, 2019 | | | |
| 020710 001 | PAROXETINE HYDROCHLORIDE; PAXIL | 6080759 | MAY 19, 2015 | | | |
| 020895 001 | PAROXETINE HYDROCHLORIDE; PAXIL | 6063927 | APR 23, 2019 | | | |
| 020885 002 | PAROXETINE HYDROCHLORIDE; PAXIL | 6080759 | MAY 19, 2015 | | | |
| 020885 003 | PAROXETINE HYDROCHLORIDE; PAXIL | 6063927 | APR 23, 2019 | | | |
| | | 6080759 | MAY 19, 2015 | | | |

PRESCRIPTION AND OTC DRUG PRODUCT
 PATENT AND EXCLUSIVITY DATA
 *PED and PED represent Pediatric Exclusivity

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | EXCLUS CODE | EXCLUS EXCLUS EXPIRES |
|------------------|--|---------------|-------------------------|-------------|-----------------------|
| 020885 004 | PAROXETINE HYDROCHLORIDE; PAXIL | 6062927 | APR 23, 2019 | | |
| 020936 001 | PAROXETINE HYDROCHLORIDE; PAXIL CR | 6080759 | MAY 19, 2015 | | |
| 020936 002 | PAROXETINE HYDROCHLORIDE; PAXIL CR | 6063927 | APR 23, 2019 | | |
| 021084 001 | PERFLUOROPOLYMETHYLISOPROPYL ETHER; SKIN EXPOSURE REDUCT | 6080759 | MAY 19, 2015 | | |
| 020698 001 | POLYETHYLENE GLYCOL 3350; MIRALAX | 5607979 | MAY 30, 2015 | | |
| 019898 002 | PRAVASTATIN SODIUM; PRAVACHOL | 6048901 | APR 20, 2019 | U-343 | FEB 17, 2005 |
| | | 5622985 | APR 22, 2014 | U-335 | |
| >ADD> | PRAVASTATIN SODIUM; PRAVACHOL | 5622985 | APR 22, 2014 | U-335 | |
| >ADD> | PRAVASTATIN SODIUM; PRAVACHOL | 5622985 | APR 22, 2014 | U-335 | |
| 019157 001 | PREDNISOLONE SODIUM PHOSPHATE; PEDIAPRED | 4448774 | DEC 22, 2002 | NPP | OCT 15, 2002 |
| 020630 001 | REMIFENTANIL HYDROCHLORIDE; ULTIVA | 5019583*PED | AUG 15, 2009 | U-156 | APR 15, 2003 |
| | | 5466700 | AUG 30, 2013 | PED | APR 15, 2003 |
| 020630 002 | REMIFENTANIL HYDROCHLORIDE; ULTIVA | 5019583 | FEB 15, 2009 | PED | JAN 12, 2002 |
| | | 5466700*PED | MAR 01, 2014 | U-156 | JUL 12, 2001 |
| | | 5019583 | FEB 15, 2009 | NPP | OCT 15, 2002 |
| | | 5466700 | AUG 30, 2013 | U-156 | APR 15, 2003 |
| 020630 003 | REMIFENTANIL HYDROCHLORIDE; ULTIVA | 5019583*PED | AUG 15, 2009 | PED | APR 15, 2003 |
| | | 5466700*PED | MAR 01, 2014 | NCE | JAN 12, 2001 |
| | | 5019583 | FEB 15, 2009 | NPP | OCT 15, 2002 |
| | | 5466700 | AUG 30, 2013 | U-156 | APR 15, 2003 |
| 020903 001 | RIBAVIRIN; REBETOL | 5019583*PED | AUG 15, 2009 | PED | APR 15, 2003 |
| 020835 001 | RISEDRONATE SODIUM; ACTONEL | 5466700*PED | MAR 01, 2014 | U-156 | JAN 12, 2002 |
| | | 6051252 | DEC 22, 2017 | NCE | JUL 12, 2001 |
| 020588 001 | RISPERIDONE; RISPERDAL | 5453425 | JUL 11, 2014 | I-292 | APR 14, 2003 |
| 020659 001 | RITONAVIR; NORVIR | 5616587 | JUL 11, 2014 | I-291 | APR 14, 2003 |
| | | 6037157 | JUN 26, 2016 | I-290 | APR 14, 2003 |
| | | 5674882 | OCT 07, 2014 | I-293 | APR 14, 2003 |
| | | 5886036 | DEC 29, 2012 | | |

PRESCRIPTION AND OTC DRUG PRODUCT
 PATENT AND EXCLUSIVITY DATA
 *PED and PED represent Pediatric Exclusivity

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|------------------|--|---------------|-------------------------|----------|-------------|----------------|
| 020823 003 | RIVASTIGMINE TARTRATE; EXELON | 4948807 | AUG 14, 2007 | U-322 | NCE | APR 21, 2005 |
| 020823 004 | RIVASTIGMINE TARTRATE; EXELON | 5602176 | FEB 11, 2014 | U-322 | | |
| 020823 005 | RIVASTIGMINE TARTRATE; EXELON | 4948807 | AUG 14, 2007 | U-322 | NCE | APR 21, 2005 |
| 020823 006 | RIVASTIGMINE TARTRATE; EXELON | 5602176 | FEB 11, 2014 | U-322 | | |
| 021025 001 | RIVASTIGMINE TARTRATE; EXELON | 4948807 | AUG 14, 2007 | U-322 | NCE | APR 21, 2005 |
| 020864 001 | RIZATRIPTAN BENZOATE; MAXALT | 5602176 | FEB 11, 2014 | U-322 | | |
| 020864 002 | RIZATRIPTAN BENZOATE; MAXALT | 5602162 | FEB 11, 2014 | U-322 | | |
| 021042 001 | ROFECOXIB; VIOXX | 6063811 | MAY 16, 2017 | U-266 | | |
| 021042 002 | ROFECOXIB; VIOXX | 6063811 | MAY 16, 2017 | U-266 | | |
| 021052 001 | ROFECOXIB; VIOXX | 6063811 | MAY 16, 2017 | U-266 | | |
| 021052 002 | ROFECOXIB; VIOXX | 6063811 | MAY 16, 2017 | U-266 | | |
| 021071 002 | ROSIGLITAZONE MALEATE; AVANDIA | 5002953 | AUG 30, 2008 | U-329 | I-289 | APR 03, 2003 |
| 021071 003 | ROSIGLITAZONE MALEATE; AVANDIA | 5741803 | APR 21, 2015 | U-329 | | |
| 021071 004 | ROSIGLITAZONE MALEATE; AVANDIA | 5002953 | AUG 30, 2008 | U-329 | I-289 | APR 03, 2003 |
| 020990 001 | SERTRALINE HYDROCHLORIDE; ZOLOFT | 5741803 | APR 21, 2015 | U-329 | | |
| 021179 001 | SEVELAMER HYDROCHLORIDE; RENAGEL | 5496545 | AUG 11, 2013 | U-246 | NCE | OCT 30, 2003 |
| 021179 002 | SEVELAMER HYDROCHLORIDE; RENAGEL | 5667775 | SEP 16, 2014 | U-246 | | |
| 020478 001 | SEVOFLURANE; ULTANE | 5667775 | SEP 16, 2014 | U-246 | NCE | OCT 30, 2003 |
| >ADD> | SOMATROPIN RECOMBINANT; GENOTROPIN | 5990176 | JAN 27, 2017 | U-246 | NCE | JUN 07, 2000 |
| >ADD> | SOMATROPIN RECOMBINANT; GENOTROPIN | 6074668 | JAN 09, 2018 | U-246 | PED | DEC 07, 2000 |
| >ADD> | SOMATROPIN RECOMBINANT; GENOTROPIN | 5990176* | JUL 27, 2017 | U-246 | | |
| >ADD> | SOMATROPIN RECOMBINANT; GENOTROPIN | 6074668* | JUL 09, 2018 | U-246 | | |
| 020280 001 | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 4968299 | JUN 28, 2008 | | I-302 | JUN 20, 2003 |
| 020280 002 | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5435076 | APR 16, 2013 | | ODE | JUN 20, 2003 |
| 020280 003 | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| 020280 004 | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| | | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| | | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| | | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| | | 4968299 | JUN 28, 2008 | | I-302 | JUN 20, 2003 |
| | | 5435076 | APR 16, 2013 | | ODE | JUN 20, 2007 |
| | | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| | | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| | | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| | | 4968299 | JUN 28, 2008 | | I-302 | JUN 20, 2003 |
| | | 5435076 | APR 16, 2013 | | ODE | JUN 20, 2007 |
| | | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| | | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| | | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| | | 4968299 | JUN 28, 2008 | | I-302 | JUN 20, 2003 |
| | | 5435076 | APR 16, 2013 | | ODE | JUN 20, 2007 |
| | | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| | | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| | | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |

PRESRIPTION AND OTC DRUG PRODUCT
 PATENT AND EXCLUSIVITY DATA
 *PED and PED represent Pediatric Exclusivity

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/ PED EXCL EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|------------------|--|---------------|--------------------------|----------|-------------|----------------|
| 020280 005 | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| | | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| 020280 008 | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| | | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| 020280 009 | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| | | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| 020280 010 | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| | | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| 020280 011 | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| | | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| 020280 012 | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| | | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| 020280 013 | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5435076 | APR 16, 2013 | | I-302 | JUN 20, 2003 |
| | | 5716338 | FEB 10, 2015 | | ODE | JUN 20, 2007 |
| 019721 001 | SOMATROPIN RECOMBINANT; NORDITROPIN | 5633352 | MAY 27, 2014 | | D-55 | APR 13, 2003 |
| 019721 002 | SOMATROPIN RECOMBINANT; NORDITROPIN | 5633352 | MAY 27, 2014 | | M-2 | DEC 01, 2002 |
| 019676 001 | SOMATROPIN RECOMBINANT; NUTROPIN | 5633352 | MAY 27, 2014 | | D-55 | APR 13, 2003 |
| 019676 002 | SOMATROPIN RECOMBINANT; NUTROPIN | 5633352 | MAY 27, 2014 | | M-2 | DEC 01, 2002 |
| 020522 001 | SOMATROPIN RECOMBINANT; NUTROPIN AQ | | | | | |
| >ADD> | | 6051259 | DEC 02, 2012 | U-340 | | |
| >ADD> | | 6051259 | DEC 02, 2012 | U-340 | | |
| >ADD> | | 6051259 | DEC 02, 2012 | U-340 | | |
| >ADD> | | 5431900 | JUL 11, 2012 | U-336 | NP | FEB 22, 2003 |
| >ADD> | | 4894445 | JAN 16, 2007 | U-337 | NP | FEB 22, 2003 |
| >ADD> | | 5324824 | JAN 16, 2007 | | NP | FEB 22, 2003 |
| >ADD> | | 4885100 | SEP 11, 2007 | | | |
| >ADD> | | 4988827 | JAN 29, 2008 | | | |
| >ADD> | | 4452774 | SEP 09, 2004 | | | |
| >ADD> | | 4894445 | JAN 16, 2007 | U-337 | | |
| >ADD> | | 5324824 | JAN 16, 2007 | | | |
| >ADD> | | 4885100 | SEP 11, 2007 | | | |
| >ADD> | | 4988827 | JAN 29, 2008 | | | |
| >ADD> | | 4680291 | JUL 14, 2004 | U-73 | | |
| >ADD> | | 4755534 | DEC 30, 2006 | U-73 | | |
| >ADD> | | 5681849 | OCT 28, 2014 | | | |
| 019785 003 | TECHNETIUM TC-99M SESTAMIBI KIT; MIRALUMA | | | | | |
| 021124 001 | TERBINAPINE HYDROCHLORIDE; LAMISIL AT | | | | | |
| 021015 001 | TESTOSTERONE; ANDROGEL | 5559269 | MAY 05, 2015 | U-318 | NDF | FEB 28, 2003 |
| 020484 001 | TINZAPARIN SODIUM; INNOHEP | | | | NCE | JUL 14, 2005 |
| 020771 001 | TOLTERODINE TARTRATE; DETROL | | | | | |

PRESCRIPTION AND OTC DRUG PRODUCT
 PATENT AND EXCLUSIVITY DATA
 *PED and PED represent Pediatric Exclusivity

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL USE EXPIRES | EXCLUS CODE | EXCLUS EXPIRES |
|------------------|-----------------------------|---------------|-----------------------------|-------------|----------------|
| >ADD> | | 4859692 | SEP 26, 2010 | NCE | SEP 26, 2001 |
| >ADD> | ZAFIRLUKAST; ACCOLATE | 5294636 | DEC 11, 2011 | I-268 | SEP 17, 2002 |
| >ADD> | | 5319097 | DEC 11, 2011 | NS | SEP 17, 2002 |
| >ADD> | | 5482963 | JAN 09, 2013 | | |
| >ADD> | | 5583152 | SEP 26, 2010 | | |
| >ADD> | ZANAMIVIR; RELENZA | 5612367 | MAR 18, 2014 | U-189 | |
| 021036 001 | ZANAMIVIR; RELENZA | | | I-294 | APR 26, 2003 |
| 020789 001 | ZONISAMIDE; ZONEGRAN | | | NCE | MAR 27, 2005 |

PATENT AND EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE PATENT AND EXCLUSIVITY COLUMNS, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 20TH EDITION FOR A FULL LISTING OF PATENT AND EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). THE CUMULATIVE SUPPLEMENT WILL LIST NEW CODES ADDED SINCE THE LAST ANNUAL EDITION.

ABBREVIATIONS

NPP NEW PATIENT POPULATION

REFERENCES

NEW DOSING SCHEDULE

D-51 OPTIONAL STARTING DOSE OF 40MG/DAY
 D-52 ALTERNATE DOSING REGIMEN OF 1250MG TWICE DAILY
 D-53 USE IN PEDIATRIC PATIENTS FROM 1 MONTH TO 16 YEARS OF AGE
 D-54 USE OF ZYBAN FOR MAINTENANCE THERAPY. TREATMENT UP TO 6 MONTHS WAS SHOWN EFFICACIOUS
 D-55 ADDITION OF A HIGHER DOSE OF NUTROPIN FOR PUBERTAL PATIENTS (PUBERTAL DOSE LESS THAN OR EQUAL TO 0.7MG/KG/WEEK)
 D-56 ADDITION OF POSTPRANDIAL DOSING
 D-57 3-HOUR INFUSION OF TAXOL GIVEN EVERY THREE WEEKS AT A DOSE OF 175MG/M2 FOLLOWED BY CISPLATIN AT A DOSE OF 75MG/M2 FOR THE FIRST-LINE TREATMENT OF ADVANCED OVARIAN CANCER
 D-58 CHANGE IN DOSING INTERVAL TO ONCE-DAILY ADMINISTRATION
 D-59 REDUCTION OF ELEVATED LDL-C IN A NEW, HIGHER STRENGTH TABLET, 0.8MG, AND FOR EXTENSION OF THE DOSAGE RANGE TO 0.8MG DAILY
 D-60 ADDITION OF A POST-OPERATIVE DOSING REGIMEN

NEW INDICATION

I-283 TO REDUCE THE INCIDENCE OF MODERATE TO SEVERE XEROSTOMIA IN PATIENTS UNDERGOING POST-OPERATIVE RADIATION TREATMENT FOR HEAD AND NECK CANCER, WHERE THE RADIATION PORT INCLUDES A SUBSTANTIAL PORTION OF THE PAROTID GLANDS
 I-286 TREATMENT OF PATIENTS WITH FREDERICKSON TYPE III
 I-287 USE OF PRAVASTATIN IN PATIENTS WITH EVIDENT CORONARY HEART DISEASE TO REDUCE THE RISK OF TOTAL MORTALITY BY REDUCING CORONARY DEATH
 I-288 CHANGES SEVERAL SECTIONS OF THE PACKAGE INSERT TO INCORPORATE STATEMENTS CONCERNING THE USE OF HIGH DOSES OF LISINAPRIL TO REDUCE THE RISK OF THE COMBINED OUTCOMES OF MORTALITY AND HOSPITALIZATION IN PATIENTS WITH CONGESTIVE HEART FAILURE
 I-289 USE OF AVANDIA IN COMBINATION WITH A SULFONYLUREA IN PATIENTS WITH TYPE 2 DIABETES MELLITUS WHEN DIET AND EXERCISE WITH EITHER SINGLE AGENT DOES NOT ACHIEVE ADEQUATE GLYCEMIC CONTROL
 I-290 TREATMENT OF CORTICOSTEROID-INDUCED OSTEOPOROSIS
 I-291 PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS
 I-292 TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS
 I-293 TREATMENT OF CORTICOSTEROID-INDUCED OSTEOPOROSIS

PATENT AND EXCLUSIVITY TERMS

NEW INDICATION

- I-294 TREATMENT OF UNCOMPLICATED ACUTE ILLNESS DUE TO INFLUENZA A AND B IN PEDIATRIC PATIENTS 7 YEARS AND OLDER WHO HAVE BEEN SYMPTOMATIC FOR NO MORE THAN 2 DAYS
- I-295 PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS FOR WOMEN WITH AN INTACT UTERUS
- I-296 LONG-TERM INTRAVENOUS TREATMENT OF PULMONARY HYPERTENSION ASSOCIATED WITH THE SCLERODERMA SPECTRUM OF DISEASE IN NYHA CLASS III AND CLASS IV PATIENTS WHO DO NOT RESPOND TO CONVENTIONAL THERAPY
- I-297 SHORT-TERM TREATMENT OF ACUTE MANIC EPISODES ASSOCIATED WITH BIPOLAR I DISORDER
- I-298 TREATMENT OF PATIENTS WITH FREDERICKSON TYPE IIA AND IIB HYPERLIPOPROTEINEMIA
- I-299 USE OF CAMPTOSAR AS A COMPONENT OF FIRST-LINE THERAPY IN COMBINATION WITH 5-FLUOROURACIL AND LEUCOVARIN FOR PATIENTS WITH METASTATIC CARCINOMA OF THE COLON OR RECTUM
- I-300 PROPHYLAXIS FOR ASTHMA IN CHILDREN 2-5 YEARS OF AGE
- I-301 TREATMENT OF SIGNS AND SYMPTOMS OF ALLERGIC CONJUNCTIVITIS
- I-302 TREATMENT OF PEDIATRIC PATIENTS WITH PRADER-WILLI SYNDROME
- I-303 INCREASING HDL-CHOLESTEROL IN PATIENTS WITH PRIMARY HYPERCHOLESTEROLEMIA AND MIXED DYSLIPIDEMIAS
- I-304 TREATMENT OF PATIENTS WITH FREDERICKSON TYPE IV
- I-305 TREATMENT OF LEVOFLOXACIN SUSCEPTIBLE STRAINS OF PENICILLIN-RESISTANT STREPTOCOCCUS PNEUMONIAE IN PATIENTS WITH COMMUNITY ACQUIRED PNEUMONIA
- I-306 INDUCTION OF SPERMATOGENESIS IN MEN WITH PRIMARY AND SECONDARY HYPOGONADOTROPIC HYPOGONADISM IN WHOM THE CAUSE OF INFERTILITY IS NOT DUE TO PRIMARY TESTICULAR FAILURE
- I-307 NEW COMBINATION USE OF METFORMIN AND INSULIN IN TYPE 2 DIABETES

MISCELLANEOUS EXCLUSIVITY CODES

- M-2 APPROVAL FOR ADDITION TO CLINICAL PHARMACOLOGY SECTION OF THE LABEL REGARDING (1) IMPROVEMENT IN BONE MINERAL DENSITY IN CHILDHOOD-ONSET ADULT GROWTH HORMONE DEFICIENT PATIENTS AND (2) INCREASES IN SERUM ALKALINE PHOSPHATASE
- M-3 ADDITION OF EFFICACY AND SAFETY INFORMATION IN WHICH FOSAMAX WAS USED CONCOMITANTLY WITH ESTROGEN ALONE OR WITH ESTROGEN PLUS PROGESTIN

PATENT USE CODE

- U-266 RELIEF OF THE SIGNS AND SYMPTOMS OF OSTEOARTHRITIS; MANAGEMENT OF ACUTE PAIN IN ADULTS; TREATMENT OF PRIMARY DYSMENORRHEA
- U-309 TREATING SJOEGREN SYNDROME
- U-310 TREATMENT OF XEROSTOMIA
- U-311 HORMONE REPLACEMENT
- U-312 PANIC DISORDER OBSESSIVE-COMPULSIVE DISORDER POSTTRAUMATIC STRESS DISORDER
- U-313 TREATMENT OF CONGESTIVE HEART FAILURE
- U-314 METHOD FOR TREATING HYPERPARATHYROIDISM WHICH COMPRISES SUPPRESSING PARATHYROID ACTIVITY
- U-315 METHOD FOR ADMINISTERING DRUG TO GASTROINTESTINAL TRACT
- U-316 METHOD OF TREATING A SUBJECT SUFFERING FROM PROSTATE CANCER
- U-317 METHOD OF USING TROGLITAZONE TO TREAT PATIENTS HAVING INSULIN RESISTANCE

PATENT AND EXCLUSIVITY TERMS

PATENT USE CODE

- U-318 TREATMENT OF PATIENTS WITH AN OVERACTIVE BLADDER WITH SYMPTOMS OF URINARY FREQUENCY, URGENCY, OR URGE INCONTINENCE
- U-319 TREATMENT OF MICROBIAL INFECTIONS
- U-320 INHIBITING OR ELIMINATING ACUTE MYELOID LEUKEMIA
- U-321 REDUCTION OF ELEVATED IPTH LEVELS IN THE MGT OF SECONDARY HYPERPARATHYROIDISM IN PATIENTS UNDERGONG CHRONIC RENAL DIALYSIS
- U-322 TREATMENT OF ALZHEIMER'S DEMENTIA
- U-323 USE AS A BILE ACID SEQUESTRANT
- U-324 METHOD OF TREATING AN ANIMAL, INCLUDING A HUMAN, SUFFERING FROM OR SUSCEPTIBLE TO PSYCHOSIS OR ACUTE MANIA EMPLOYING OLANZAPINE
- U-325 METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED CONDITIONS, INCLUDING "BIPOLAR DISORDER NOS" EMPLOYING OLANZAPINE
- U-326 METHOD OF TREATING SCHIZOPHRENIA AND BIPOLAR DISORDER
- U-327 METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED PSYCHOTIC CONDITIONS EMPLOYING OLANZAPINE
- U-328 METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED CONDITIONS INCLUDING "A PSYCHOTIC CONDITION" EMPLOYING AN OLANZAPINE POLYMORPH
- U-329 USE OF AVANDIA AS MONOTHERAPY, IN COMBINATION WITH METFORMIN, AND IN COMBINATION WITH SULFONYLUREAS TO IMPROVE GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES MELLITUS
- U-330 TREATMENT OF NAUSEA AND VOMITING
- U-331 METHOD OF TREATING HYPERLIPIDEMIA WITH NICOTINIC ACID BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT
- U-332 TREATMENT OR PREVENTION OF BRONCHOSPASM
- U-333 METHOD OF TREATING OCULAR HYPERTENSION
- U-334 TREATMENT OF EXCESSIVE FEMALE FACIAL HAIR
- U-335 USE OF PRAVASTATIN SODIUM FOR SECONDARY PREVENTION OF CORONARY EVENTS IN MEN AND WOMEN WHO HAVE HAD A MYOCARDIAL INFARCTION AND HAVE NORMAL CHOLESTEROL LEVELS
- U-336 DIAGNOSTIC RADIOIMAGING
- U-337 USE OF CARDIOLITE/MIRALUMA KIT FOR THE PREPARATION OF TC99M SESTAMIBI
- U-338 METHODS FOR TREATING DISTURBANCES OF MOOD, DISTURBANCES OF APPETITE, DEPRESSED MOOD, OR CARBOHYDRATE CRAVING ALL ASSOCIATED WITH PREMENSTRUAL SYNDROME
- U-339 PREVENTION OF CARDIO-TOXICITY CAUSED BY THE ADMINISTRATION OF DOXORUBICIN
- U-340 THE LONG TERM TREATMENT OF GROWTH FAILURE DUE TO LACK OF ADEQUATE ENDOGENOUS GROWTH HORMONE SECRETION IN CHILDREN
- U-341 METHOD FOR ENHANCING THE TREATMENT OF ... LATE LUTEAL PHASE DYSPHORIC DISORDER
- U-342 METHOD FOR TREATMENT OF LATE LUTEAL PHASE DYSPHORIC DISORDER
- U-343 REDUCTION OF INTESTINAL GAS, CRAMPING AND ANORECTAL IRRITATION

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